



Attorney Docket No. 00497-08  
Declaration dated December 2, 2005  
Responsive to Office Action dated June 2, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney		}	Customer No.	34444
Docket No.	00497-08	}		
		}	Art Unit:	1654
Applicant:	Zhonglin Hao, et al.	}		
		}	Examiner:	Billy D. Chism
Serial No.	10/809,654	}		
		}		
Filing Date:	March 25, 2004	}		
		}		
Title:	Sperm Specific Proteins			

Certificate of Mailing Under 37 CFR §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service using First Class Service under 37 C.F.R. § 1.8 on the date indicated below and is addressed to Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Date: December 2, 2005

  
Sue Ann Carr

Declaration of John C. Herr, Ph.D. under 37 C.F.R. § 1.131

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

I, John C. Herr, declare:

1. I am an inventor of the above-referenced patent application.

2. I hold a Ph.D. from the University of Iowa and completed postdoctoral training at the University of Washington. I am currently Professor of Cell Biology, Professor of Urology, and the Dean's Special Assistant for Development, School of Medicine, University of Virginia. I am also Director of the Lymphocyte Culture Center and Director of the Center for Research in Contraceptive and Reproductive Health at the University of Virginia. I am the co-author of approximately 150 peer-reviewed publications, 20 book chapters, and 160 abstracts, many of which are concerned with testis specific proteins, fertility, and contraception. I have had

continuous research funding since 1979 by various federal agencies and private funding groups and currently I am the principal investigator or co-investigator of four federal grants and one private grant. I am a member of several professional societies, have served on the editorial board of four journals, and have served as a reviewer for many scientific journals. I have served on numerous study sections for various federal agencies.

2. I have read and understand the Office Action dated June 2, 2005.

3. I understand that the Examiner has rejected claims 19, 20, and 29, drawn to a peptide having SEQ ID NO:16, or modifications thereof, as allegedly anticipated by U.S. 2002/0102604 (Edwards et al.) under 35 U.S.C. § 102(e). This Declaration is being submitted with a response to the Office Action dated June 2, 2005. Accompanying this Declaration are sixty-eight (68) pages of evidentiary documents labeled Exhibits 1-68, respectively. A copy of my curriculum vitae, labeled Exhibit A, is also included with the Declaration.

4. I present below a description of studies and their dates performed by me, my co-inventors, or under my direct supervision showing that the present application identified and characterized a protein we called C58, which has the amino acid sequence SEQ ID NO:16. By this 37 C.F.R. § 1.131 Declaration, I, John C. Herr, an inventor of the present invention, assert that the presently claimed invention was invented before Edwards et al. was filed. This Declaration and the accompanying Exhibits (1-68) submitted herewith serve to document and verify the fact that we invented C58 (SEQ ID NO:16) before Edwards et al. even filed their first provisional application. The cited Edwards application publication claims the benefit of a provisional application filed December 8, 1999. Based on the discussion presented below, and the Exhibits submitted herewith, it can be seen that we invented by at least October 5<sup>th</sup>, 1999, which is at least two months before the December 8, 1999 filing date of the provisional application from which the Edwards application publication claims priority. Therefore, the instant invention for patent as claimed by the Applicants cannot be anticipated under 35 U.S.C. § 102(e) by Edwards et al. Examiner is reminded that the present application is a Divisional application and that two other proteins were prosecuted in the parent application (now issued) encompassing the peptide of SEQ ID NO:2 and the nucleic acid sequence encoding SEQ ID NO:2, and another active Divisional application encompassing SEQ ID NO:9. All of the work

encompassing the various proteins was occurring simultaneously and was included in the provisional application we filed January 19, 2000.

5. **The evidentiary documentation** provided with the Declaration comprises 68 (sixty-eight) photocopied pages of the laboratory notebook of one of my co-inventors, Dr. Jagathpala Shetty, who performed much of the work of the present application. The 68 pages were all dated at the time of data entry and are labeled as Exhibits 1 through 68. All of the laboratory notebook pages also indicate the name of the person entering the data, namely Jagathpala Shetty. The pages are dated from August 12, 1999 to December 18, 1999. The invention disclosure was then prepared by the Applicants and submitted to the University of Virginia Patent Foundation. A provisional patent application was then prepared and filed on January 19, 2000. Therefore, the entire process of identifying the protein called C58, isolating it, sequencing it, performing bioinformatic analyses, protein expression and northern blot analyses, was performed from August 12, to December 18, 1999. The data were then collated, an Invention Disclosure was prepared, and a patent application based on the Invention Disclosure was prepared and filed within a month of the last dated laboratory notebook page submitted herewith.

6. **Timetable of Experiments**: The experiments related to identifying and isolating C58, sequencing the peptide named C58, which has the sequence of SEQ ID NO:16, and characterizing C58, are summarized chronologically below to demonstrate when the sequence was first discovered, and to demonstrate diligence in completing the invention. Note that the application as filed included the identification, isolation, sequencing, and characterization of C58, as well as two other proteins. However, it should be particularly noted that the complete nucleotide and amino acid (SEQ ID NO:16) sequences of C58 are first demonstrated in the laboratory notebook of Dr. Shetty on October 5 and 6, 1999, on pages 82-84 (Exhibits 35-37).

7. **The studies to identify and isolate C58** were performed as follows: Testis extracts were subjected to two-dimensional gel electrophoresis and spots of interest were identified. The spot identified as C58 (see Exhibit 1) was cored out, subjected to tryptic digest, and microsequenced. The first page of evidence supplied with the Declaration (Exhibit 1; page 39 of Dr. Shetty's laboratory notebook, dated August 12, 1999) has a copy of an image of a two-dimensional gel which is labeled with numbers to identify locations of various proteins, one of

which was C58, which had partially sequenced on August 11, 1999, including C58 (the name of the protein comprising SEQ ID NO:16). The spots had been cored from the gel, subjected to tryptic digests, and subjected to microsequencing, the results of which are indicated in Exhibit 2, dated August 15, 1999. Exhibit 2 demonstrates the four peptide tryptic digest components of spot/band C58. Exhibit 3 (page 42 of the notebook, dated August 15, 1999) depicts the use of an EST chosen based on the tryptic digests. Exhibit 4 demonstrates the PCR strategy using the EST and Exhibit 5 demonstrates the sequence of the PCR-derived EST partial sequence for C58. Exhibit 6 (page 50, dated September 7, 1999) summarizes the cloning of C58 and the beginning of several weeks work of screening the C58 library (Exhibits 6 to 79; dated September 7, 1999 to September 30, 1999). To summarize, Exhibits 4 to 34, comprising photocopies of Dr. Shetty's laboratory notebook pages (pages 43, 48, 50-54, 56-75, and 77-80, respectively; dated August 26, 1999 to September 25, 1999), demonstrate a series of experiments and data involving further preparation and isolation of the C58 nucleic acid and peptide.

8. **The studies to sequence C58** were performed as follows: A nucleic acid sequence which encodes the C58 peptide was obtained from the studies described in Exhibits 1-34, and that sequence is demonstrated in Exhibit 35 (page 82 of the notebook, dated **October 5, 1999**). The sequence for the nucleic acid encoding the amino acid sequence of SEQ ID NO:16 (C58 protein) included the ORF of the sequence. The sequence was examined and Exhibit 37 (page 84 of the notebook, dated **October 6, 1999**) presents the deduced 124 amino acid residue sequence of SEQ ID NO:16. Therefore, it can be seen that the nucleic acid sequence encoding SEQ ID NO:16 was obtained by **October 5, 1999**, and at that point the nucleic acid sequence was capable of being used to deduce the amino acid sequence, which amino acid sequence (i.e., SEQ ID NO:16) was indeed demonstrated on Exhibit 37, dated **October, 6, 1999**. These two dates disclosing the C58 sequences are much **earlier** than the December 8, 1999 filing date of the Edwards provisional application.

9. **Bioinformatic Analyses and further characterization of C58**: Next, a series of bioinformatic analyses were performed to compare the new C58 nucleic acid and amino acid (SEQ ID NO:16) sequences to other proteins known in the art and to further characterize the protein. Then, a series of experiments and analyses were performed to ensure that the complete protein had been isolated and sequenced, expression vectors were prepared and



analyzed, cells were transformed with the expression vectors and analyzed (see Exhibits 38-52, summarizing experiments and analyses performed until November 23, 1999). For example, Exhibit 52 (the carbon copy page of page 100, with a sequence pasted in; dated November 23, 1999), summarizes a series of analyses which had been performed and demonstrates the sequence alignment of C58 with proteins of the Ly6/UPAR family of proteins. Exhibit 53 is a photocopy of a page from a new notebook (page 1, dated November 29, 1999), summarizing a series of experiments analyzing protein expression from the bacterial vector. These experiments are illustrated in Exhibit 53 to Exhibit 63 (comprising notebook pages 1-6, and 9-13, respectively; dated November 29, 1999 to December 15, 1999).

10. **Verification that C58 is testis-specific:** A series of experiments were performed to verify that the newly discovered C58 protein, which was discovered in testis, was indeed a testis specific protein. To that end, a series of probes and reagents were prepared and Northern blot analyses were performed and indeed demonstrated testis specific expression of C58. The results of these experiments are summarized in Exhibits 64 to 68 (comprising photocopies of Dr. Shetty's laboratory notebook pages 14-18, respectively, dated December 15 to December 18, 1999).

11. **Preparation of Invention Disclosure and Preparation and Filing of a Provisional Patent Application:** The C58 (SEQ ID NO:16) experiments performed as of December 18, 1999 were then included as part of an invention disclosure, along with the results of two other proteins which were included in the original application. The invention disclosure was submitted to the University of Virginia Patent Foundation, reviewed, and prepared and filed as a provisional patent application on January 19, 1999. Thus, it can be seen that from the time of the last C58 experiment included in the application, the time required to prepare and submit the invention disclosure and prepare and file a provisional patent application was only one month. These acts all indicate diligence in inventing, reducing to practice, and filing an application based on the three proteins which were included in the original provisional application.

Based on the description provided above, and the documentary evidence provided herewith in the form of 68 Exhibits, I assert that the present invention was clearly not anticipated by Edwards et al. under 35 U.S.C. § 102(e). I further assert that the diligence requirement was met in all aspects of identifying, sequencing, and characterizing the C58

protein (SEQ ID NO:8), preparing an invention disclosure, and preparing and filing a provisional patent application.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issuing thereon.

John C. Herr  
John C. Herr

12-2-05  
Date

**List of Exhibits for Identifying, Isolating, Sequencing, and Characterizing Protein C58  
(Exhibit A and Exhibits 1-68):**

**Exhibit A-** Curriculum Vitae of Dr. John C. Herr

**Exhibits 1-68 Description (Date, Page Number in Laboratory Notebook, and Content)**

- |    |  |
|----|--|
| 1  | 8/12/99, page 39, provides labeled image of 2D-gel identifying testis proteins by number, including C58 protein.   |
| 2  | 8/15/99, report number 400, sequence analysis of 22 2D gel bands from 8/11/99, summarizing in Table 1 the sequences of the four tryptic peptide fragments of C58 cored from the gel of Exhibit 1.  |
| 3  | 8/15/99, page 42, shows selection of EST used based on tryptic peptide sequence of C58.  |
| 4  | 8/26/99, page 43, demonstrates the PCR strategy and results of the PCR preparation and analysis using the EST shown in Exhibit 3.  |
| 5  | 9/7/99, page 48, demonstrates the results of sequencing the partial C58 nucleic sequence obtained from Exhibit 4.  |
| 6  | 9/7/99, page 50, (as well as Exhibits 7-34) demonstrates cloning of C58/screening of library using vectors prepared from Exhibits 4 and 5. This Exhibit and the Exhibits through Exhibit 34 include screening the libraries twice (1° and 2° screening) and preparing to sequence C58 (sequencing twice to ensure accuracy). |
| 7  | 9/8/99, page 51, demonstrates further studies related to cloning C58.  |
| 8  | 9/8/99, page 52, demonstrates progression of cloning C58   |
| 9  | 9/9/99, page 53, demonstrates dilutions and sketches of plates used in the plating/cloning.  |
| 10 | 9/9/99, page 54, describes transfection studies for cloning C58  |
| 11 | 9/9/99, page 56, describes labelling DNA   |
| 12 | 9/10/99, page 57, describes library screening, including membrane lifting and cross-linking  |

- 13 9/10/99, page 58, describes library screening, including preparation of plates  
and protocol for prehybridization protocol
- 14 9/10/99, page 59, describes membrane handling and addition of  
prehybridization solution
- 15 9/10/99, page 60, describes preparation and use of DNA purifying column, etc.
- 16 9/10/99, page 61, describes collection of DNA and hybridization
- 17 9/11/99, page 62, describes washing the membrane
- 18 9/11/99, page 63, describes preparing for exposing the membrane
- 19 9/11/99 and 9/13/99, page 64, describes exposing the membrane to film and  
preparation of exposed film
- 20 9/13/99, page 65, describes marking spots to be picked from plates, etc.
- 21 9/14/99, page 66, describes secondary screening
- 22 9/14/99 and 9/15/99, page 67, describes DNA labeling and secondary lifting
- 23 9/15/99, page 68, describes prehybridization and hybridization protocols
- 24 9/16/99 and 9/17/99, page 69, describes washing and exposing membranes and  
developing film
- 25 9/20/99, page 70, describes cell inoculation and clone picking
- 26 9/20/99, page 71, continues the protocol from Exhibit 25 up to plating on LB-  
agar plates
- 27 9/21/99, page 72, describes observing plates inoculated on previous day and  
inoculation of cultures
- 28 9/22/99, page 73, describes isolating DNA from plasmids
- 29 9/22/99, page 74, further describes the procedure begun in Exhibit 28
- 30 9/22/99, page 75, describes plasmid digestion and preparation for inserting new  
insert
- 31 9/23/99, page 77, describes sequential digestion of DNA
- 32 9/24/99, page 78, describes agarose gel electrophoresis of digested DNA and  
disclose an image of the gel
- 33 9/30/99, page 79, discusses the results of the ongoing sequencing and further  
preparation of bacterial cultures
- 34 9/25/99, page 80, describes plasmid isolation and preparation of plasmid DNA
- 35 10/5/99, page 82, provides a summary of the sequence analysis which had been  
ongoing for one of the C58 clones, and provides the entire nucleic acid

sequence of C58 had been found, including the ORF. The sequence was then used to deduce the amino acid sequence.

- 36 10/6/99, page 83, discusses the various attempts at sequencing different C58 clones
- 37 10/6/99, page 84, provides both the nucleic acid and amino acid (SEQ ID NO:16) sequences of C58, including the entire 124 amino acid sequence
- 38 10/29/99, page 85, describes ongoing work for preparing C58 ORF DNA.
- 39 11/2/99, page 86, describes the use of PCR to generate C58 complete with ORF and provides an image of the results of a gel analysis of the products
- 40 11/16/99 and 11/17/99, page 89, demonstrates ongoing studies to prepare and amplify DNA
- 41 11/17/99, page 90, demonstrates another image of an agarose gel
- 42 11/18/99 and 11/19/99, page 91, demonstrates further cloning, including preparation of competent cells and transformation
- 43 11/19/99, page 92, further describes the protocol which begins on Exhibit 42
- 44 11/19/99 and 11/20/99, page 93, describes plating of cells and picking colonies
- 45 11/22/99 (appears to have been 11/21), page 94, describes plasmid DNA isolation
- 46 11/21/99 and 11/22/99, page 95, describes the continuation of the procedure of the previous page (Exhibit 45), as well as resuspending isolated DNA
- 47 11/22/99 and 11/23/99, page 96, demonstrates plasmid digestion and electrophoretic analysis of the digested DNA
- 48 11/22/99, page 97, describes preparation of DNA from clone 4 for use in sequencing and then more bioinformatic analysis
- 49 11/23/99, page 98, has a taped in sequence analysis which was performed using the DNA from Exhibit 48 and completed on 11/29/99 at 14:35 checking the insert and petc58.promoter.dna sequence based on 2 enzyme cuts (NCOI and XHOI).
- 50 11/25/99, 11/26/99, and 11/29/99, page 99, describe cell culture, plasmid DNA isolation, and electrophoretic analysis from pET28b-C58-Novablue (#4)
- 51 11/23/99, page 100, provides summaries taped into the notebook which were the results of ongoing analyses of the proposed architecture of C58 (see upper

figure, i.e., taped in Fig. 8) and a taped in schematic (lower panel) suggesting C58 is GPI-anchored

- 52 11/23/99, page 100 (this was the carbon page used to tape an additional insert),  
demonstrates the results of a sequence alignment study of C58 comparing it  
with other Ly6/UPAR family members
- 53 11/29/99, 11/30/99, and 12/1/99, page 01 (new notebook), demonstrates the first  
of several studies to express the C58 protein in bacteria. The bacterial  
expression studies continue through Exhibit 63 (new notebook page 13).
- 54 12/1/99, page 02 (new notebook), demonstrates a continuation of Exhibit 53  
summarizing the bacterial expression studies
- 55 12/3/99, page 03 (new notebook), demonstrates bacterial lysate preparation and  
electrophoresis as part of the ongoing expression studies
- 56 12/3/99, page 04 (new notebook), isolation and preparation of protein for  
electrophoresis
- 57 12/4/99 and 12/6/99, page 05 (new notebook), electrophoresis and preparation  
for western blotting
- 58 12/4/99, page 06 (new notebook), demonstrates an electrophoretic image of the  
results of the first bacterial expression studies, and no expression was found
- 59 12/10/99, 12/11/99, 12/12/99 and 12/13/99, page 9 (new notebook),  
demonstrate preparation of different clones
- 60 12/13/99, page 10 (new notebook), demonstrates transformation
- 61 12/15/99, page 11 (new notebook), demonstrates the protocol of a new  
electrophoretic analysis of bacterial lysates with the C58 clone
- 62 12/15/99, page 12 (new notebook), demonstrates an image of a gel prepared  
from Exhibit 61
- 63 12/15/99, page 13 (new notebook), demonstrates the map summarizing lane  
loading to examine bacterial expression of C58
- 64 12/15/99, page 14 (new notebook), demonstrates the protocol and preparation of  
reagents to be used in Northern blot analyses to determine whether C58 is testis  
specific
- 65 12/15/99, page 15 (new notebook), provides copies of the various protocols  
used in the Northern blot analyses of C58 expression

- 66 10/16/99 (should be 12/16/99), page 16 (new notebook), describes probe preparation for Northern blot analysis of C58 expression and the hybridization and wash steps
- 67 12/16/99, page 17 (new notebook), continues from Exhibit 66 describing the wash procedures, and film exposure
- 68 12/18/99, page 18 (new notebook), demonstrates an image of the Northern blot prepared in Exhibits 66 and 67, demonstrating that C58 message is detectable in testis, but not in spleen, thymus, prostate, ovary, small intestine, colon, or leukocytes.



EXHIBIT A

**JOHN CHRISTIAN HERR**

**Curriculum Vitae**

Current Status: Professor of Cell Biology  
Professor of Urology  
Other Titles: Director of the Lymphocyte Culture Center  
Director of the Center for Research in Contraceptive and Reproductive Health  
Dean of School of Medicine's Special Assistant for Development

Address

Department of Cell Biology  
University of Virginia Health System  
School of Medicine P.O. Box 800732  
Charlottesville, VA 22908-0732  
Tel: (434) 924-2007  
Fax: (434) 982-3912  
E-Mail: [jch7k@virginia.edu](mailto:jch7k@virginia.edu)  
<http://hsc.virginia.edu/medicine/basic-sci/cellbio/crgcv/>

Personal Data

Birthdate: June 29, 1948  
Birthplace: Dubuque, Iowa  
Citizenship: U.S.; Ethnic Origin: Caucasian [Northern European]  
U.S. Social Security Number: 480-56-3234  
U.S. Passport #: 012851562 [expires August 8, 2006]  
Marital Status: Married to Mary Jo Herriman, two children:  
Christian Craig Herr (b. 6/23/83); Austin King Herr (b. 9/18/88)

Education

Summer Program:	1968	Hopkins Marine Station, Stanford University [Phycology (algae, plankton)]
B.A.	1970	Grinnell College, Grinnell, Iowa [General Biology, Education]
Ph.D.	1978	University of Iowa, Anatomy & Cell Biology [Advisor: P.M. Heidger]
Postdoctoral	1978-81	University of Washington, Seattle [Advisor: E.M. Eddy; reproductive immunology]



## Academic Experience

1. 1974-1978 National Institutes of Health Trainee in Anatomy, University of Iowa, Dept. Anatomy.
2. 1978-1979 Fellow: NICHD Interdisciplinary Training Program in Developmental Biology, University of Washington
3. 1979-1981 NIH National Research Service Award Postdoctoral Fellowship, University of Washington, Department of Biological Structure. "Sperm Surface Antigens"
4. 1981-1987 Assistant Professor, Department of Anatomy & Cell Biology, University of Virginia, Charlottesville, Virginia.
5. 1982-present Director, University of Virginia Lymphocyte Culture Center.
6. 1987 -1992 Associate Professor Anatomy & Cell Biology, University of Virginia.
7. 1990-1996 Director, Biotechnology Training Program.
8. 1991-present Director, NIH Center for Research in Contraceptive and Reproductive Health [formerly Center for Recombinant Gamete Contraceptive Vaccinogens].
9. 1992-present Professor of Cell Biology, University of Virginia.
10. 1999-present Dean's Special Assistant for Development
11. 2003-present Professor of Urology

## Professional Affiliations

Sigma Xi

American Association of Anatomists

American Society for Cell Biology

American Society for Reproductive Immunology

American Society of Andrology

Society for the Study of Reproduction

International Society for the Immunology of Reproduction

## Areas of Current Interest

Cell biology of gametogenesis: specifically: differential gene expression during spermatogenesis and oogenesis. Reproductive immunology: postvasectomy autoimmunity. Applied research: contraceptive vaccine development; identification of contraceptive drug targets; infertility diagnostics; male contraception; spermicides; cancer and forensic biomarkers.

## Service to Societies

- |           |   |
|-----------|---|
| 2004-pres | Awards Committee, Am. Soc. Reprod. Immunology                         |
| 2003-pres | Public Affairs Committee, American Society Andrology                  |
| 2003      | Program Committee, American Society of Andrology, 2005 Annual Meeting |
| 2002      | Program Committee, American Society Andrology, 2004 Annual Meeting    |
| 2001      | Organizing Committee, Testis Workshop, Phoenix, AZ                    |
| 2001      | Councilor - American Society for Reproductive Immunology              |
| 1998-00   | Councilor - International Society for Immunology of Reproduction      |

1998 Abstract Review Committee, Society for the Study of Reproduction  
 1996-97 Host, First International Conference on Experimental and Clinical Reproductive Immunobiology, October, 1997, Charlottesville, VA  
 1995-96 Organizing Committee, 1996 Meeting of American Society of Reproductive Immunology  
 1994-95 Organizing Committee, Sixth International Congress of Reproductive Immunology  
 1993 Organizing Committee, Serona Symposium, Immunology of Reproduction, August 26-29, 1993, Boston, MA  
 1993 Abstract Review Committee, Society for the Study of Reproduction  
 1993-94 President, American Society for Reproductive Immunology  
 1991 Abstract Review Committee, American Society of Andrology  
 1991 Organizer of the 11th Annual Meeting of the Am. Society for Immunology of Reproduction, Charlottesville, VA  
 1989-94 Councillor- American Society for Immunology of Reproduction  
 1988-91 Educational Affairs Committee - American Association of Anatomists  
 1987 Centennial Fund Raising Committee, American Association of Anatomists  
 1985-88 Committee member, Planning Committee for 1987 Centennial Meeting, American Association of Anatomists  
 1985 Committee member, Criteria for Admissions to AAA Directory  
 1985-86 Committee member, Nominations Committee, American Association of Anatomists  
 1984 Committee member, Committee to Improve the Annual Meeting, American Association of Anatomists  
 1983-86 Chairman, Advisory Committee of Young Anatomists, American Association of Anatomists

#### Awards

1995 Munksgaard Senior Investigator Award, American Society for Reproductive Immunology, Washington, D.C., July 22, 1995  
 1999 Christopher J. Henderson Inventor of the Year Award, University of Virginia Patent Foundation, April 26, 1999  
 2000 Virginia's Outstanding Scientist 2000 Award, March 27, 2000  
 2001 The Burroughs Wellcome Visiting Professorship in Reproductive Biology, University of Guelph, Ontario, Canada. Jan 29-Feb 2, 2001  
 2002 The Distinguished Alumnus Award for Achievement-University of Iowa, May 30, 2002  
 2004 The Raymond O. Berry Memorial Lectureship – Texas A&M University, April 2, 2004  
 2004 The Small Business Innovation Research Commercialization Breakthrough Award, Virginia Center for Innovative Technology, October 13, 2004 Arlington, VA

#### Editorial Boards

1986-1998	Anatomical Record
1988-2000	Journal of Reproductive Immunology
1991-1994, 1997-1998	American J. of Reproductive Immunology
2000-2004	Biology of Reproduction

#### Reviewer for Journals

PNAS

International J. of Cancer

International J. of Andrology

Journal of Cell Science

Journal of Cell Biology

Nature Biotechnology

Life Sciences

Journal of Histochemistry and Cytochemistry

Journal of Andrology

Reproduction, Fertility, Development

Biology of Reproduction

American Journal of Anatomy

Journal of Investigative Urology

Developmental Biology

Journal of Reproduction and Fertility

Journal of Urology

Biochemical Pharmacology

Molecular Human Reproduction

Journal of Immunology

Fertility and Sterility

Protein Expression and Purification

Journal of Clinical Investigation

Experimental Cell Research

### Study Sections

2004 Review Intramural Program: Laboratory of Biosystems and Cancer, National Cancer Institute, September 19-21, 2004

2004, Special Emphasis Panel "NRSA Applications", March 10 and 11, 2004

2004, NIH Minority Biomedical Research Support Panel ad hoc reviewer, Feb. 10, 2004

2003, NIH Conference Panel: "Strategic Planning Meeting for the Fogarty International Center Programs" Dec. 12, 2003

2003, Chairman NIH Special Emphasis Panel: Synthesis and Testing of Nonsteroidal and Nonhormonal Male Contraceptive Agents, Sept. 17, 2003

2002, NIH Special Emphasis Panel, JWG, May 2002.

2002, NIH Special Emphasis Panel, NRSA Applications, March 5, 2002.

2002, NIH Special Emphasis Panel, JWG, May 2002.

2002, NIH Special Emphasis Panel, NRSA Applications, March 5, 2002.

2001, NIH Special Emphasis Panel, P30 Center, Washington State, July 24.

2001, NIH Special Emphasis Panel, February 19, Support Contracts for Contraceptive and Reproductive Health Branch [CRHB]

2000, NIH Special Emphasis Panel, June 27-28, P30 Center Washington State

2000, External Reviewer, Jeffress Memorial Trust

1999, Ad hoc Reviewer, SBIR Study Section, US Dept. Agriculture.

1999, External Reviewer for Royal Society of Great Britain.

1998 Member, National Institute of Allergy and Infectious Diseases Task Force on Immunology.

NIH Special Emphasis Panel Behavioral Medicine Study Section, Dec 11, 1998

External Reviewer for NIH Intramural Programs, Fall 1998  
 External Reviewer for Wellcome Trust, 1994, 1995, 1997, 1999, 2000  
 External Reviewer for Israel Science Foundation, 1997, 1998  
 External Reviewer for WHO Program in Reproductive Research and Training, 1995  
 Member, National Cancer Institute Special Study Section "Scalable GMP Production", April 22, 1994;  
 October 4, 1994  
 Member, NIH-NICHD Special Study Section - P50 Center, Aug. 23-25, 1993  
 Member, NIH-NIGMS Biotechnology Training Programs Study Section and 2 Site Visit Teams, Fall  
 1993  
 Member, Immunocontraceptive Working Group, U.S.A.I.D., 1992-1993  
 Chairman, NIH Special Study Section, "Development of a Contraceptive Vaccine, October 9, 1992  
 Member, Molecular Immunology and Vaccine Development Panel of the National Task Force on the  
 NIH Strategic Plan, June 23-25, 1992  
 Member, Expert Panel on Wildlife Damage and Population Regulation, U.S. Dept. Agriculture, April,  
 1992  
 Member, Immunocontraceptive Working Group, Contraceptive Research and Development Program,  
 USAID, September, 1991  
 Member, NIH-NICHD Special Study Section-Program Project, "A Coordinated Program in  
 Reproductive Biology," May, 1991  
 Member, United States Agency for International Development Contraceptive Research and  
 Development Program Working Group, May, 1990  
 Member, NIH-NICHD Population Research Committee, Aug. 1990  
 Member, NIH - NIDDK Study Section, Program Project: "Experimental Models of Gene Therapy,"  
 December 11-13, 1989  
 Member, NIH - NIDDK Special Study Section, Small Business Innovative Research, Fall 1988  
 Member, NIH - NICHD Special Study Section - Population Research Center, April 6-9, 1988  
 Ad hoc reviewer, NSF Developmental Biology Study Section

#### International Service

2004- Program Committee, "Advances and Challenges in Reproductive Health in the Post  
 Genomic Era" held Jan 9-12, 2005, Mumbai, India.

In 1990, Dr. Herr received a grant from USAID to organize a course, "Molecular Biology of  
 Human Spermatogenesis" which was taught in March of 1990 at the National Institute of Immunology  
 in New Delhi, India. This 16 day course covered methods of cloning genes from the human testis and  
 was attended by students, postdoctoral fellows and faculty members from universities throughout India.  
 A fully functional rDNA laboratory was transported to New Delhi and was donated to the Indian  
 government at the conclusion of the course. Dr. and Mrs. Richard Wright assisted in this effort.

In 1992, a grant from the NIH supported a workshop at the Institute for Chemical Biology in  
 Calcutta, India. Dr. Herr's lab organized a two-week course, including Dr. Herr, Ken Klotz, and Alex  
 Freemerman, also from Dr. Herr's laboratory. The course covered basic methods of molecular biology  
 including RNA isolation and cDNA library construction. Laboratory equipment for molecular biology  
 training was assembled in Virginia for the course and donated to the Institute at the conclusion of the  
 course.

In 1995, Dr. Herr served as a visiting professor in Cairo, Egypt where he lectured at Ain Shaims University, Al-Azhar University, and Cairo University and visited the Marine Biology Station at Suez. The topics of his lectures and discussions were the trends and opportunities in contraceptive vaccine research and development.

In 1998, Dr. Herr organized a team to teach a laboratory in the Frontiers in Reproduction Course at Woods Hole, Mass. The course was attended by 16 international scholars in 1998 and was again taught in 1999.

In 2000, Dr. Herr was appointed as a member of the Indo-US Joint Working Group comprised of members from the NIH, State Department, USAID and U.S. scientists as well as Indian counterparts in government and academics. This group fosters collaborative scientific efforts between the two countries and reviews bilateral grant applications.

#### Boards of Directors of Corporations and Foundations

1983-1987	Humagen, Inc
1992-Present	ContraVac, Inc
1998-2008	University of Virginia Patents Foundation
2005	Translational Research Partnership with the Wallace H. Coulter Foundation

#### University Committees Served

2004 [Fall]	Chair Review Committee, Department of Obstetrics/Gynecology
2004-2005	CRCRH Faculty Search Committee, [Chairman]
2004	Department of Urology Faculty Search Committee
2004-2005	School of Medicine Search Committee for Associate Dean for Clinical Research
2002-2003	School of Medicine Resources Committee
2002-2004	UVA Technology Commercialization Working Group (Provost's Office)-Leadership sub-committee; Infrastructure sub-committee
2002-	Chairman, Henderson Inventor of the Year Committee
2001-present	Faculty Development Council
2000-2001	Search Committee, Development Office, UVA Health System, Director of Development for Immunology Research
2000-2001	Search Committee, Dept. Cell Biology, Faculty Replacement
1999-present	Medical Advisory Council to Dean School of Medicine
1999-present	UVA Research Parks Communications Council
1999-present	Health Sciences Corporate and Foundation Relations Advisory Council
1999-2001	Science and Technology 2020 Planning Commission
1998-present	Chairman, Histology Research Core Advisory Committee
1998-present	Library Capital Campaign Committee
1998-present	Chairman, Faculty Advisory Committee-Univ. of Virginia Patent Foundation
1997-1998	LCME Accreditation Task Force
1996-1998	Dean's Task Force on US News Survey of Medical Schools
1991-2001	Faculty Task Force on the School of Medicine Capital Campaign
1994-1998	Faculty Task Force for Biomedical Research
1994-1995	Institutional Research Policy Advisory Committee

1994-1997	Search Committee for University/Industry Research Coordinator, Office of Vice Provost for Research
1994-1995	Chairman, Faculty Forum for Scientific Research
1992-2001	Executive Committee Molecular Medicine Training Program
1993-1995	Member, Faculty Forum for Scientific Research
1991-1992	Committee for P-30 Grant for Reproductive Center Cores
1991-1997	Selection Committee for the University of Virginia Inventor of the Year Award [Dr. Richard Edlich, chair]
1991-1996	Graduate Advisors Committee
1990-1996	Executive Committee, Program Director, Biotechnology Training Program
1982-present	Committee for Lymphocyte Culture Core
1983-1988	Committee for FACS
1982-1983	Committee for Reproductive Biology Program Project (Gene Oliphant, Chairman)
1982	Committee for Organizing MAC Grant
1983-1986	Preclinical Committee (J. David Deck, Chairman)
1984-1988	Cancer Center Organizing Committee Program Project for Cancer Research Unit (R. Wagner - T. Parsons)
1987-1988	Committee for Reproductive Biology Training Grant
1987-1993	Search Committee, Department of Anatomy and Cell Biology
1985-1990	Gynecologic Cancer Committee
1989	Jefferson Award Committee (Department of Continuing Education)

#### Community Service

1999-pres	Biotechnology Curriculum Advisory Committee of Piedmont Virginia Community College
2000-2001	Founding member and Mate, Ship 19, Sea Scouts, Boy Scouts of America

#### In Training Teaching Activities

1975	Gross Anatomy for Medical Students, University of Iowa
1976	Principles of Human Anatomy for Nurses, University of Iowa
1976	Neuroanatomy, University of Iowa
1978	Histology for Medical Students, Univ. of Washington
1979	Musculoskeletal System, University of Washington
1979	Gross Anatomy for Dental Students, University of Washington

#### Overview of Teaching Activities at UVA

1981-82	Gross Anatomy for medical students; Course director: Anat. 506 Experimental Morphology
1982-83	Anat. 805 Special Topics in Dev. Anatomy Gross Anatomy for medical students; Course director: Anat. 506; Experimental Morphology, Biol 495, Anat 999.
1983-84	Gross Anatomy for medical students; Course director: Anat. 506 Experimental Morphology, Anat. 999

1984-85	Gross Anatomy for medical students; Director, Anat. 605 Experimental Methods; Anat. 595; Anat. 599; participant, Anat. 802 (Reprod. Biology), Anat. 999, Biol 495
1985-86	Gross Anatomy for medical students; Course Director, Anat. 805 Topics in Developmental Biology, participant in Anatomy 605, Anat. 999
1986-87	Gross Anatomy for medical students; participant in Anatomy 605, Anat. 999
1987-88	Gross Anatomy for medical students; Experimental Methods (Anat. 605); Advances in Reproductive Biology (Anat. 802), Anat. 999, Biol 495
1988-89	Gross Anatomy for medical students, Experimental Methods, Anat. 999
1989-90	Gross Anatomy for medical students, Experimental Methods, Anat. 999
1990-91	Gross Anatomy for medical students, Experimental Methods, Anat. 999
1991-92	Gross Anatomy for medical students, Experimental Methods, Anat. 999
1992-93	Gross Anatomy for medical students, Experimental Methods, Anat. 999
1993-94	Gross Anatomy for medical students, Experimental Methods, Anat. 999
1994	Anatomy 805 Advances in Reproductive Biology
1994	Research Ethics GSAS 710
1995-98	Gross Anatomy for medical students
1998	Colloquium in Reproductive Biology-Gene Regulation of Spermatogenesis
2002	Gross Anatomy for medical students
2003	Gross Anatomy for medical students
2004	Gross Anatomy for medical students

#### Graduate Students Supervised and Supported (Thesis Advisor)

<u>Years</u>	<u>Student</u>	<u>Positions following Ph.D.</u>
1982-1987	Lisa Kisalus	Post-doctoral fellow: Harvard Medical School, Associate Director, Symposia, Serono, Inc.
1983-1987	Rob McGee	Post-doctoral fellow: NIEHS, Research Triangle, N.C. 1987-89. MD: Bowman-Grey 1990-1994. Residency - Pathology.
1985-1987	Nagiu Fares	Agency for Int. Dev. Peace Fellow from Egypt; conducted his thesis work with Dr. Herr. Currently Professor of Biology, Department of Biology, Faculty of Science, Ain Shams Univ., Cairo, Egypt.
1985-1989	Hal Handley	Post-doctoral fellow: Scripps Inst., La Jolla, CA. Currently Senior Scientist in biotechnology company-Maxim, Inc.
1987-1992	James Foster	Post-doctoral fellow: Univ. Pennsylvania, Dept. Ob-Gyn. Instructor, Haverford College. Currently Assistant Professor, Dept Biology, Randolf-Macon College, Ashland, VA.

1987-1991	Ming Chen Shen	Marriage and children.
1990-1992	Kelly Beecher	M.S. [1992], Research Assistant, Dept. Neuroscience, Univ. Kansas
1990-1994	Alex Freemerman	Postdoctoral fellow, cancer biology, Medical College of Virginia. Research Associate, Univ. Arizona. Currently Research Assistant Professor, Duke University, Dept. Surgery.
Began 1991	Cecelia Videus	Ph.D, Aug 1998: Winner Young Investigator Award; Am. Soc.Reprod. Immunol, 1996; entered Darden Business School Fall 1998. Summer internship 1999 at Pfizer. MBA, 2000. Currently investment banker specializing in biotechnology.
Began 1994	Lisa Norton	Ph.D, Aug 2000. Received 1998 Langman Award from Am. Soc. Anatomists for best grad student paper presented at FASEB meeting. Received 1999 Michael J. Peach Award for Outstanding Graduate Student, University of Virginia. Application Scientist, Combi Matrix, Seattle, WA.
Began 1999	Theresa Thompkins	Received 5 year NIH Predoctoral Fellowship for Minority Students for her MD/PHD. In the Summer of 2000 she received a National Merit Award.

#### Postdoctoral Fellows

7/1/83-6/30/84	Mark Sigman, M.D., Currently Professor of Urology, Brown Univ.
7/1/84-6/30/85	Bob Evans, M.D., Urology Resident - Dr. Evans' work with Dr. Herr was presented at the Mid Atlantic Urology Meetings on October 3, 1985 in Philadelphia where Dr. Evans won 1st place for the best research paper presented by a Urology Fellow. He later went on to win second place at the National Urology Meetings in 1986. Dr. Evans' paper also won the Annual Medical Society of Virginia House Officer Prize for 1986. Dr. Evans is currently in private practice.
5/1/85-8/31/86	Nana Hussein Riad, Ph.D.- Professor and Chairman of Biology, Ains Shams University, Cairo, Egypt. Received Fullbright Scholarship to work with Dr Herr. Dr. Riad came to learn immunocytochemical procedures at light and EM levels. Dr. Riad returned in 1998 to UVA with a second Fullbright scholarship to learn molecular biology techniques.



5/1/86-7/31/86 Madhu Joshi, Ph.D. - Busch Scholar on Sabbatical, Professor of Anatomy, University of North Dakota, Fargo, N.D. Dr. Joshi came to Dr. Herr's lab to learn hybridoma techniques.

9/1/88-12/31/94 Mona Homyk, Ph.D. - subsequently worked for Humagen Fertility Diagnostics, Toxicology Regulatory Services, and currently, Pharmaceutical Research Associates.

7/1/88-93 Richard Wright, Ph.D. completed a DVM in 1998 at Virginia Tech and is practicing veterinary medicine in private practice.

3/1/89-6/30/03 Barbara Kurth, Ph.D., Senior Scientist, Associate Director Primate Models Core, Center for Research in Contraceptive and Reproductive Health.

7/1/90-6/31/91 David Mburu, DVM, WHO sponsored fellowship in molecular biology - postdoc in Australia.

7/1/90-8/31/91 Anil Suri, Ph.D., U.S.A.I.D. sponsored fellowship in spermatogenesis. Current position, Associate Professor, Natl. Institute Immunology, New Delhi, India. Dr. Suri has received USAID funding to return to Dr. Herr's lab for joint research in subsequent years. Dr. Herr currently supports a joint research project through his Mellon twinning grant. In 1999 Dr. Herr and Dr. Suri received a grant from the Indo-US Program. Dr. Suri returns to the Herr lab for a 2 month sabbatical each year.

9/1/90-8/31/91 Linsong Li, M.D., Postdoctoral Fellowship-University of Washington Department of Medicine.

10/5/92-6/31/95 Prabhakara Reddi. In 1992, Dr. Reddi was awarded a two-year Rockefeller Fellowship to work with Dr. Herr. He currently serves as Associate Director of the Bioprocess Core in Dr. Herr's Center and holds an appointment as Research Assistant Professor in the Department of Cell Biology. His NIH R29 grant received a 7.6% score and was funded in 1999 for 5 years. Dr. Herr also applied for and received a Mellon Foundation Junior Investigator Award for Dr. Reddi. In 2004 Dr. Reddi received an independent NIH R01 and a tenure track Assistant Professorship in the Department of Pathology at UVA.

10/5/92-1994 Dimpy Koul - U.S.A.I.D. CD&RI Fellow. Fogarty Fellow. Currently, post-doc at Baylor.

2/11/93-12/12/98 Soren Naaby-Hansen, M.D. Dr. Naaby-Hansen is an obstetrician who worked as a Mellon Foundation Fellow. He began an Asst. Professorship at the Ludwig Cancer Institute in London on January 1, 1999, where he continues collaboration with the Herr lab.

5/11/93-7/1/94 Zhang Jian, WHO Fellow. Returned to China to his previous Senior Scientist position.

6/15/93-6/30/03	Michael Wolkowicz, Ph.D - Mellon Foundation Fellowship. Instructor in Cell Biology. Head, Molecular Biology Group, Center for Research in Contraceptive and Reproductive Health.
9/15/93-2/28/97	Milena Mihailova, Ph.D - NIH Fellow. Not currently employed due to illness. Returned to Bulgaria, her home country.
6/1/94-4/17/02	Alan Diekman, Ph.D - NRSA Awardee, subsequently received NIH SBIR grant, Became Res. Assistant Professor of Cell Biology. NIH R01 received 0.9% percentile and 5 years of funding beginning on August 1, 1998. Currently, Assistant Professor of Biochemistry and Molecular Biology, Univ. of Arkansas Medical School, May 1, 2002.
7/1/94-6/30/02	Anne Westbrook-Case, Ph.D - NIH Traineeship, Mellon Fellowship, Berlex Fellow. Research Associate, Center for Research in Contraceptive and Reproductive Health. Currently: Senior Informative Scientist, National Library of Medicine, NCBI, NIH June 17, 2002.
1/28/95-4/1/03	Scott Coonrod, Ph.D - NIH Postdoctoral Fellowship. Dr. Coonrod held a Research Assistant Professor position in Cell Biology at the University of Virginia from 2001-2003. He received a 10% score on a NIH R01 grant which was funded December 1, 1999 for 5 years. On April 1, 2003 Dr. Coonrod began as an Assistant Professor of Genetic Medicine, Cornell Weill Medical School, NY., NY.
4/23/95-5/1/96	Vrinda Khole, Ph.D - WHO Fellowship - Dr. Khole and Dr. Herr subsequently collaborated under a WHO grant to Dr. Khole. Dr. Khole is Associate Professor at the Institute of Science, Bombay. Dr. Khole returned to Dr. Herr's lab in January 2000 for a 1 year sabbatical supported by the Fogarty International Center at NIH. Dr. Khole received a Mellon Twinning Grant from CONRAD in 2001. She had a two month sabbatical in the Herr lab in 2002 (Fall). In 2003 she was appointed deputy Director of the Institute for Research in Reproductive Health in Bombay.
7/1/95-8/1/96	Li Bin, Ph.D - PAN AM Health Organization Fellow specializing in chemical engineering. He has returned to China, his home country.
9/1/96-12/31/97	Hiroaki Shibahara, M.D. - training was sponsored by the Japanese government. Returned to Assistant Professorship, Hyogo Medical College, Japan. Currently Associate Professor of Obstetrics and Gynecology, Jichi Medical School, Japan.
9/1/96-6/30/2003	Arabinda Mandal, Ph.D - Fogarty Fellowship, Berlex Fellowship. 2003 - Instructor in Cell Biology.
11/15/96-present	Jagathpala Shetty, Ph.D - Fogarty Fellowship. In 2003 advanced to Senior Scientist in cell Biology.

7/1/98 - 2000	Tod C. McCauley, Ph.D - Berlex Fellowship / NIH Postdoctoral Trainee. Currently Research Associate, University of Missouri.
7/23/98-10/1/01	Buer Sen, Ph.D - Fogarty Fellowship. Currently, Postdoctoral Fellow, Emory University.
9/1/98-02/01/02	Friederike Jayes, Ph.D - Berlex Fellowship. Currently: Scientist, National Institute Environmental Health Sciences, Research Triangle Park, NC.
10/1/99-present	Zhonglin Hao, MD, Ph.D - Berlex Fellowship. Currently: Resident, Dept. of Internal Medicine, Medical Center of Central Georgia
7/1/00-6/30/2002	Mike Coppola, Ph.D - Berlex Fellowship. Director of Research, ContraVac, Inc.
10/1/00-present	Young-Hwan Kim, Ph.D - Fogarty Fellowship.
2/1/03-present	Kula Nand Jha, Ph.D – Fogarty Fellowship.
4/1/01-present	Dr. Belen Herrero - Berlex Fellowship.
5/1/02-present	Pamela Schoppee, Ph.D – Berlex Fellow
6/1/02-present	Kim Fralix, Ph.D - NIH Postdoctoral Trainee 1992-1993. In 2003 (June 1) Dr Fralix received a LALOR Fellowship.
1/9/02-present	Silvia Pullido, Ph.D – Berlex Fellow
5/1/03-present	BingFang Xu, Ph.D – NIH Fellow
7/1/03-present	Geeta Vanage, Ph.D – Fogarty Fellow- Associate Professor, National Institute for Research in Reproductive Health, Mumbai, India
9/1/03-2/29/04	Alina Domagala, Ph.D – Fulbright Fellow- Researcher, Polish Academy of Sciences
9/1/03-present	Susan Sleight – Berlex Fellow
9/1/03-present	Jayasimha Rao – Fogarty Fellow
4/04-present	Sandeep Ranpura – Fogarty Fellow
1/26/04-present	Wei He, MD., Ph.D – Fogarty Fellow
4/01/04-3/30/05	Dr. Mangeet Sharma-Fogarty Fellow
4/01/04-present	Dr. Monica Sachedev-Fogarty Fellow

11/07/04-present	Yanfeng Li, MD, Ph.D.-Fogarty Fellow
10/07/04	Christian Gaudreault, Ph.D., CRCRH Fellow

#### Competitive Grants Awarded Previously

1979-81	NIH Postdoctoral Fellowship - "Isolation of Sperm Surface Antigens" NRSA
1981	University of Virginia Biomedical Research Support Award #5 S07RR 05431-20, \$9,950 start-up funds: "Sperm Isoantigens Recognized by Monoclonal Antibodies"
1981	American Cancer Society Small Institutional Grant Committee, \$5,000, pilot funds for "Anti-Sperm Antibody Production from Human X Human Hybridomas"
1982-present	Pratt Endowment Support for Establishing and Maintaining the Lymphocyte Culture Center
1982-85	Principal Investigator, NIH 1 R01 HD16767-01->03, "Antisperm Monoclonal Antibodies Isolated Post-Vasectomy." Project period: 9/30/82-9/29/85, \$155,004 Direct Cost
1983-86	Principal Investigator, NIH 1 R01 HD17489 "Protein Synthesis and Secretion by Human Decidual Cells." Project Period: 4/1/83 - 10/30/86; \$107,495 Direct Cost
1983-84	Principal Investigator, FBI Contract 115744 "Monoclonal Antibodies in Forensic Diagnosis," 10/1/83 - 9/31/84. Direct Cost: \$60,000
1983-86	Co-Investigator, NSF PC-8309364 "Secretion in the Epididymis" 12/83-11/86, \$205,000, Dr. Charles Flickinger, P.I.
1984-90	Co-Investigator, NIH HD18825; "Vasovasostomy: Morphology, Physiology and Immunology," 8/1/84 - 9/31/90. Total direct cost: \$311,053, Dr. Stuart Howards, P.I.
1984	Principal Investigator - Endotronics Industrial Collaborative Project, \$130,000 industrial contribution - Acusyst 150, MMCM
1984-87	Co-Investigator and Principal Investigator (1985-86) NIH HD-12335 "Developmental Aspects of Mammalian Calcium Transport", 12/1/84-11/30/87, \$233,531 Direct Cost, Dr. Elizabeth Bruns, Principal Investigator
1985-87	Collaborator - "Diabetes in the B.B. Rat" (NIH). Dr. Herr supervised one 1/2 time technician and one 3/4 time technician and directed histological aspects of this study. David Benjamin - P.I.
1985-86	Principal Investigator FBI Grant "MHS-5 & HSA Monoclonals" 2/1/85-1/31/86 Direct Cost \$89,274
1985-88	Principal Investigator NIH HD16767-04->06 "Monoclonal Antibodies to Human Sperm" \$175,359 Direct Cost 9/29/85-8/31/88
1986-88	Principal Investigator "Monoclonal Antibodies to the Tumor Inhibitor PB-1" Center for Innovative Technology/Philadelphia Biologicals \$47,994 2/1/87-1/31/88
1986-88	Principal Investigator, FBI Contract, "Monoclonal Antibodies to Vaginal Secretions" \$91,942 Direct Cost

1988-91 Principal Investigator, "Cloning and Purification of a Sperm Membrane Immunogen" 2/1/88-1/31/91, NIH HD23789 Direct Costs: \$346,564

1987-89 Principal Investigator, "Molecular Biology of Human Spermatogenesis," 8/1/87-7/31/89, Center for Innovative Technology and Humagen, Inc. Direct Costs: \$237,002

1987-91 Principal Investigator, "Optimization of Immunoglobulin Secretion from Mouse and Human Hybridomas," Technology Development Center, \$204,754 Direct Costs

1987-90 Principal Investigator, "Purification of Recombinant Immunogen and Scale Up of Expression System," Technology Development Center \$88,670 Direct Costs

1988-89 Principal Investigator, "Toward Development of a Monoclonal Antibody Derivatized Sperm Cell Affinity Bead", Lifecodes Corp. \$44,193 Direct Costs, 9/1/88-4/1/89

1988 Principal Investigator, "Scale-up of Hybridomas" Flow Laboratories \$23,000 Industrial Equipment Donation

1988-90 Principal Investigator, C.J. Flickinger Co-Principal Investigator, "Localization of a Human Sperm Contraceptive Vaccine Immunogen", Mellon Foundation \$85,000 11/1/88-4/31/90

1989 Principal Investigator, "World Health Organization Sperm Workshop", \$11,000 11/1/89 - WHO

1990 Principal Investigator, "Workshop: Cloning and Sequencing Human Testicular Genes" CONRAD/U.S. A.I.D. \$30,000

1991-1992 Principal Investigator, "Infertility Testing Under GLP", Ortho Pharmaceuticals, total direct costs 1/1/91-9/18/92, \$316,050

1991-1994 Co-Investigator, "Vasovasostomy: Morphology, Physiology and Immunology", Stuart Howards, PI, NIH HD18825, 4/1/91->3/31/95, \$344,549 total direct costs

1990-1995 Principal Investigator/Program Director, "Multidisciplinary Training Program in Biotechnology" NIH GM08401 \$482,798 total direct costs, 9/1/90->6/30/95

1991-1994 Principal Investigator, "Baboon Infertility Testing of Recombinant SP-10 Vaccine" NIH HD 23789-04-06, 8/1/91->7/31/94, \$301,639 total direct costs

1991-1994 Principal Investigator, "Incidence of SP-10 Antibodies in Sera and Secretions of Infertile Couples". United States Agency for International Development \$237,636 direct costs, 10/1/91-12/31/93

1992-1996 Principal Investigator, "Interdisciplinary Training in Contraceptive Vaccine Development" Mellon Foundation, \$700,000 1/1/93-4/1/96

1993-1995 Principal Investigator, "Baboon Fertility Trials of Recombinant Baboon SP-10", CONRAD, \$301,746 direct costs, 9/1/93-2/28/96

1996-1997 Principal Investigator, "Postdoctoral Fellowship on Behalf of A.B. Diekman", NIH, \$28,600 direct costs, 6/1/96-5/31/97

1991-2002 Principal Investigator, "Center for Recombinant Gamete Contraceptive Vaccinogens" NIH U54-HD29099, \$6,789,297 direct costs, 9/1/91 - 8/31/96; 9/1/96 - 2/28/97, \$713,849 direct cost; 3/1/97 - 2/30/98, \$1,863,707 total direct cost; 3/1/98 - 2/29/99, \$1,896,955 total direct cost; 3/1/99 - 2/28/00, \$1,674,101 total direct cost; 3/1/00 - 2/28/01, \$1,510,254 total direct cost.

1995-2000	Principal Investigator, D43 TW/HD00654 "Translational Contraceptive Research for Indian Postdocs", NIH Fogarty Center, 9/30/95 - 9/29/00 \$1,069,952 total direct cost
1996-1999	Principal Investigator, "Multi-Institutional Interdisciplinary Postdoctoral Training", Mellon Foundation, \$550,000, 4/1/96-3/31/99
1997-1998	Principal Investigator, ContraVac, "Recombinant Antibodies as Intra-Vaginal Spermicides," \$9,200 direct costs, 10/1/97-3/31/99
1997-1999	Principal Investigator, CIT, "Recombinant Antibodies as Intra-vaginal Spermicide", \$20,000 total direct cost, 11/1/97 - 10/31/99
1996-2001	Principal Investigator, "Isolation and Characterization of Genes Encoding Sperm Surface Antigens by Screening Human Testis Expression cDNA Library: Identification of a Candidate Molecule(s) for Development of Contraceptive Vaccine," Conrad MFG-96-19, \$113,606 total costs, current year \$27,018 total direct cost 10/1/96-09/30/01
1999-2002	Principal Investigator, "Training and New Research Initiatives in Contraceptive Development", Mellon Foundation, \$250,000 total direct costs, current year, 4.1.99-3.31.02
1999-2002	Principal Investigator, "Carbohydrate Immunocontraceptive Epitopes Identified in a Neoglycolip Library Derived from the Human SpermGlycocalyx", Mellon Foundation, Junior Investigator Award on behalf of Alan B. Diekman \$360,000 total direct cost current year, 4.1.99-3.31.02
1998-2002	Co-Investigator, "Cellular Regulation of the Developing Testis Following Vasal Ligation", NIH DK45179-01 \$98,953 direct costs current year, 7/1/98-6/30/02

#### Current Funding

1998-2004	Principal Investigator "Program of Research and Development for Sperm Antigen" \$4,507,530 total direct cost, \$1,210,645 annual direct cost, Sponsor: Schering, AG
1998-2004	Principal Investigator, NIH HD35523 "Immunological Mechanisms in Human Female Infertility", \$970,474 direct costs, 7/1/98-7/31/2004
2000-2004	Co-Investigator, "Characterization of Protein Tyrosine Phosphorylation during Human Sperm Capacitation", Mellon Foundation, \$420,000 total direct cost, current year, 4.1.00-3/31/2004
2000-2005	Co-Investigator, NIH HD38353 "Oolemmal Proteomics", \$214,062 total direct cost, current year, 2/1/00-1/30/05
2000-2005	Principal Investigator, NIH, "Research Training in Reproduction for Asian Fellows", \$1,152,189 total direct cost, current year 9/30/00 - 9/25/05
2001-2004	Principal Investigator, "Contraceptive Vaccines for Dogs and Cats Based on Egg Membrane Antigens", The Kenneth A. Scott Charitable Trust, \$62,300 total direct cost, year 1.
2001-2006	Principal Investigator, "Contraceptive Vaccines for Dogs and Cats Based on Egg Membrane Antigens". Genetics Savings and Clone, \$775,520 total direct cost; \$96,200 total direct cost, year 1.
2000-2003	Principal Investigator, "Sperm Binding Magnetic Beads for Forensic PCR/DNA Analysis", National Institute of Justice, \$206,440 total direct cost, current year 10/1/2000-12/31/2003

2000-2004	Principal Investigator, NIH U54-HD29099 "Center for Recombinant Gamete Contraceptive Vaccinogens" \$1,723,054 total direct cost, 3/1/01 - 2/29/04
2001-2004	Principal Investigator, "Spermatid Specific transcription factors as targets for novel male contraceptives." \$420,000 total direct cost, Andrew W. Mellon Foundation Junior Investigator Award on behalf of P. P. Reddi
2002-2004	Principal Investigator, "Training and Research Infrastructure in Contraceptive Development." \$250,000 total direct cost, Andrew W. Mellon Foundation
2003-2008	Co-Investigator, "Cellular Regulation in Genitourinary Development" Project 4: development and regulation of Antimicrobial Peptides in the GU Tract. \$150,000.00 total direct cost, current year, 7/1/2003-6/30/2008 NIH
2004-2009	Co-Investigator, "Antimicrobial Proteins Secreted by the Epididymis" \$180,000 total direct cost, 5/15/2004 – 2/28/2009.

#### Preceptor on Training Grants and Program Projects

1982-present	Participant in the Developmental Biology Training Grants and the Cell and Molecular Biology Training Grant
1984-present	Participant in the National Cancer Institute Training Grant
1987-present	Participant in National Cancer Institute Program Project "Oncogenes and Development"
1988-present	Participant in Urology Training Grant
1988-present	Participant in Reproductive Biology Training Grant
1991-present	Participant in the Diabetes Center Grant
1992-1999	Participant in P30 Center Core Grant for Reproductive Sciences

#### Publications

##### Journal Articles

1. Herr, John C., and J. R. Ellison 1973 Drosophila salivary chromosomes as test system for antinuclear antibody assay. Clin. Exp. Immunol. 15: 451-456.
2. Martin, Lynn, John C Herr, B.A., William Wanamaker, M.D., and Steven Kornguth, Ph.D. 1974 Demonstration of specific antineuronal nuclear antibodies in sera of patients with myasthenia gravis. Indirect and direct immunofluorescence. Neurology 24: 680-683.
3. Herr, John C. 1976 Reflexive gap junctions. Gap junctions between processes arising from the same ovarian decidual cell. J. Cell Biol. 69: 495-501.
4. Larsen, William J., Paul M. Heidger, and John C. Herr 1976 "Central fold" or true junctional profile. J. Cell Biol. 71: 333.
5. Herr, John C. and Paul M. Heidger, Jr. 1977 Decidual cell secretion, a unique mode of exocytosis. Energy Research & Developmental Conference Report-TIC No. 77-504, pp. 88-94.
6. Herr, John C., Paul M. Heidger, Jr., James R. Scott, John W. Anderson, Louis B. Curet, and Harland W. Mossman 1978 Decidual cells in the human ovary at term. 1. Incidence, gross anatomy and ultrastructural features of merocrine secretion. Am. J. Anat. 152: 7-27.

7. Herr, John C., and Paul. M. Heidger, Jr., 1978 A freeze-fracture study of exocytosis and reflexive gap junctions in human ovarian decidual cells. *Am. J. Anat.* 152: 29-43.
8. Herr, John C., Charles E. Platz, M.D., Paul M. Heidger, Jr., Louis B. Curet, M.D., and C. M. Platz 1979 Smooth muscle within ovarian decidual nodules: a link to leiomyomatosis peritonealis disseminata? *Obstet. & Gynec.* 53: 451-456.
9. Herr, John C., and E. M. Eddy 1980 Detection of mouse sperm antigens by surface labeling and immunoprecipitation approach. *Biol. Reprod.* 22: 1263-1274.
10. Allison, Stuart. A., John C. Herr, and J. Michael Schurr 1981 Structure of viral 29 DNA condensed by simple triamines. A light scattering and electron microscopy study. *Biopolymers* 20: 469-488.
11. Vernon, Robert B., Charles H. Muller, John C. Herr, Frederick A. Feuchter, and E. M. Eddy 1982 Epididymal secretion of a mouse sperm surface component recognized by a monoclonal antibody. *Biol. Reprod.*, 26: 523-535.
12. Eddy, E. M., J. C. Herr, F. A. Feuchter, R. B. Vernon, C. H. Muller, and B. A. Fendersen 1982 The heterogeneity of the sperm surface as analyzed with monoclonal antibodies. *Cell Differentiation*, 11: 303-304.
13. Herr, John C., Jackson E. Fowler, Stuart S. Howards, Mark Sigman, William M. Sutherland, Deborah J. Koons 1985 Human antisperm monoclonal antibodies constructed postvasectomy. *Biology of Reproduction*, 32: 695-711.
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1. Flickinger, C.J., J.C. Herr, R.S. McGee, R.J. Evans, W.M. Sutherland, M. Sigman, T.A. Summers, D.R. Spell, D.J. Conklin 1990 Dynamics of a human seminal vesicle specific protein. Proceedings International Workshop on Seminal and Sperm Specific Proteins in Honor of T. Mann, September, 1989. Andrologia 22, Suppl 1, 142-154.
2. Freerman, A.J., R.M. Wright, C.J. Flickinger, J.C. Herr 1994 Update on the tissue specificity of the acrosomal protein SP-10: A contraceptive vaccine candidate molecule. Proceedings of the 8th Annual Meeting of the Japanese Society for the Immunology of Reproduction. Y. Tsunoda, ed. p. 1-8.

#### Patents Developed at Virginia and Held by UVA Patent Foundation (updated 2/05)

##### **A. Issued U.S. Patents**

1. Inventors: J.C. Herr, M. Sigman and W. Sutherland  
Title: "Monoclonal Antibody to MHS-5: a New Probe for Sexual Assault Analyses"  
UVAPF Docket no. 0272-01 (Herr-MHS-5)  
Filed June 5, 1985  
U.S. Patent 4,741,998 Issued May 3, 1988
2. Inventors: J C. Herr, M. Sigman, and W. Sutherland  
Title: "Monoclonal Antibody to MHS-5; a New Probe for Sexual Assault Analysis"  
UVAPF Docket no. 0272-02 (Herr-MHS-5)  
Filed April 21, 1987  
U.S. Patent 5,047,508 Issued Sept. 10, 1991
3. Inventors: J.C. Herr and D. Benjamin  
Title: "Monoclonal Antibodies and Method of Identifying Species Using the Same"  
UVAPF Docket no. 0278-01 (Herr-HSA-1)

Filed July 16, 1985

U.S. Patent 4,735,898 Issued April 5, 1988

4. Inventors: J.C. Herr and R. M. Wright  
Title: "Human Intra-Acrosomal Sperm Antigen"  
UVAPF Docket no. 0215-02 (Herr-Sprmagp)  
Filed on Feb. 16, 1990  
US Patent 5,436,157 Issued July 25, 1995
5. Inventors: J.C. Herr and R.M. Wright  
Title: "Primate Intra-Acrosomal Sperm Antigen for Use in a Contraceptive Vaccine"  
UVAPF Docket no. 0215-04 (Herr-Sprmagp)  
Filed Aug. 18, 1984  
U.S. Patent 5,602,005 Issued Feb. 11, 1997
6. Inventors: J.C. Herr and R.M. Wright  
Title: "Primate Intra-Acrosomal Sperm Antigen for Use in a Contraceptive Vaccine"  
UVAPF Docket no. 0215-05 (Herr-Sprmagp)  
Filed Oct. 30, 1995  
U.S. Patent 5,753,231 Issued May 19, 1998
7. Inventors: J. C. Herr and R. M. Wright  
Title: "Human Sperm Diagnostic"  
UVAPF Docket no. 215-13 (Herr-Sprmdia)  
Filed April 25, 1994  
U.S. Patent 5,605,803, Issued Feb. 25, 1997.
8. Inventors: J.C. Herr, A.B. Diekman, E. Norton, and A. Westbrook-Case  
Title: "Purified Sperm Surface Antigen, Monoclonal Antibody Therefor and Applications Therefor"  
UVAPF Docket No. 216-01 (Herr-Sprmdia)  
Filed June 28, 1996  
U.S. Patent 5,830,472 Issued Nov. 3, 1998.
9. Inventors: J.C. Herr, A.B. Diekman, V.A. Westbrook-Case, and E. Norton  
Title: "Purified Sperm Surface Antigen, Monoclonal Antibody Therefor and Applications Therefor"  
UVAPF Docket No. 216-03 (Herr-Sprmdia)  
Filed Feb. 23, 1998  
U.S. Patent 6,258,364 Issued July 10, 2001
10. Inventors: P.P. Reddi, C.J. Flickinger, J.C. Herr  
Title: "Methods and Composition for Modulating Spermatogenesis"  
UVAPF Docket no. 00271-04 (Herr-Mouse)  
Filed June 25, 1999  
U.S. Patent 6,355,480 Issued on March 12, 2002
11. Inventors: Z. Hao, J.C. Herr, F. Jayes, J. Shetty, and M. Wolkowicz  
Title: "Sperm Specific Proteins"  
UVAPF Docket no. 00497-08 (Herr-NIH)  
PCT/US01/01717 filed Jan. 19, 2001  
Pending U.S. Divisional Application no. 10/809,654 (off of 10/181,642 Filed March 25, 2004)  
U.S. Patent 6,924,121 Issued on Aug 2, 2005



12. Inventors: J.C. Herr, P. Visconti, and Z. Hao  
 Title: "Human Testis Specific Serine/Threonine Kinase 1&2"  
 US Patent 6,946,275 B2  
 Issued Sept. 20, 2005  
 UVAPF Docket no. 00623-07 (Herr-Kinase)  
 PCT/US01/46803 Filed Nov. 9, 2001  
 U.S. Application no. Filed May 9, 2003
13. Inventors: J.C. Herr, S.C. Coonrod, and P. Wright  
 Title: "Egg-Specific Surface Proteins"  
 US Patent 6,962,988  
 Issued November 8, 2005  
 UVAPF Docket no. 00498-07 (Herr-MOP/CD9)  
 PCT/US01/01718 Filed Jan. 19, 2001  
 Pending U.S. Application no. 10/181,612 Filed July 18, 2002

## **B. Issued Foreign Patents**

14. Inventors: J.C. Herr and R.M. Wright  
 Title: "Human Intra-Acrosomal Sperm Antigen for Use in a Contraceptive Vaccine"  
 UVAPF Docket nos. 0215-08-10, 12, 19-30 (Herr-Sprmagp)  
 16 Foreign Patents Issued in Denmark (461177), Norway (312594), Canada (2,0505,910), Australia (649609), Sweden (461,177), Spain (461177), Switzerland (461177), France (461177), Austria (461177), Germany (461177), United Kingdom (461177), Luxembourg (461177), Netherlands (461177), Italy (461177), Belgium (461177), and Liechtenstein (461177)
15. Inventors: J.C. Herr, A.B. Diekman, E. Norton, and V.A Westbrook-Case  
 Title: "Purified Sperm Surface Antigen, Monoclonal Antibody Therefor and Applications Therefor"  
 UVAPF Docket nos. 216-05-7, 10, 15, 16 (Herr-Sprmagp)  
 6 Foreign Patents Issued in Israel (127,764), Czech Republic (293040), Australia (722559), Eurasian Patent Office (199900067K), Poland (186809), Slovakia (281505)
16. Inventors: J.C. Herr, S. Naaby-Hansen, and C. Flickinger  
 Title: "Method for the Production of Vaccines Against Cell Surface Proteins"  
 UVAPF Docket no. 00217-04 (Herr-Vocprod)  
 1 Foreign Patent Issued in Australia (743703) Issued May 16, 2002

## **C. Pending U.S. National Stage Patent Applications**

15. Inventors: J.C. Herr, K. Klotz, and A. Diekman  
 Title: "Sperm Cell Selection Systems for Forensic DNA Analysis of the Male Component"  
 UVAPF Docket no. 00474-03 (Herr-Bead)  
 PCT/US00/31771 Filed Nov. 17, 2000  
 Pending U.S. Application no. 10/146,552 Filed May 15, 2002
16. Inventors: J.C. Herr, A. Mandal, F. Jayes, J. Shetty, and M. Wolkowicz  
 Title: "Sperm Specific Lysozyme Like Proteins"  
 UVAPF Docket no. 00489-08 (Herr-Lysozym)  
 PCT/US01/01716 Filed Jan. 19, 2001  
 Pending U.S. Application no. 10/181,611 Filed July 18, 2002

17. Inventors: J.C. Herr, S. Naaby-Hansen, M. Wolkowicz, A. Mandal, and Sen Beur  
Title: "CBP86, a Sperm Specific Protein"  
UVAPF Docket no. 00492-07 (Herr-CBP86)  
PCT/US01/01715 Filed Jan. 19, 2001  
Pending U.S. Application no. 10/181,638 Filed July 19, 2002
18. Inventors: J.C. Herr, E. J. Norton, and A. B. Diekman  
Title: "Recombinant Antibody Directed Against the Human Sperm Antigen"  
UVAPF Docket no. 00415-03 (Herr-RASA)  
PCT/US00/19843 Filed July 21, 2000  
Pending U.S. Application Nationalized no. 10/031,783 Filed May 2, 2002
19. Inventors: J.C. Herr, J. Shetty, M. Wolkowicz, F. Jayes, and Z. Hao  
Title: "Sperm Specific Proteins"  
UVAPF Docket no. 00497-07 (Herr-NIH)  
PCT/US01/01717 filed Jan. 19, 2001  
Pending U.S. Application Nationalized no. 10/181,642 Filed March 25, 2004
20. Inventors: Z. Hao, J.C. Herr, F. Jayes, J. Shetty, and M. Wolkowicz  
Title: "Sperm Specific Proteins"  
UVAPF Docket no. 00497-08 (Herr-NIH)  
PCT/US01/01717 filed Jan. 19, 2001  
Pending U.S. Divisional Application no. 10/809,654 (off of 10/181,642 Filed March 25, 2004)
21. Inventors: Z. Hao, J.C. Herr, F. Jayes, J. Shetty, and M. Wolkowicz  
Title: "Sperm Specific Proteins"  
UVAPF Docket no. 00497-09 (Herr-NIH)  
PCT/US01/01717 filed Jan. 19, 2001  
Pending U.S. Divisional Application no. 10/809,655 (off of 10/181,642 Filed March 25, 2004)
22. Inventors: J.C. Herr, P. Visconti, and Z. Hao  
Title: "Human Testis Specific Serine/Threonine Kinase 1&2"  
UVAPF Docket no. 00623-07 (Herr-Kinase)  
PCT/US01/46803 Filed Nov. 9, 2001  
Pending U.S. Application no. 10/438,339 Filed May 9, 2003
23. Inventors: J.C. Herr, P. Visconti, Z. Hao, and G. Kopf  
Title: "Human Testis Specific Serine/Threonine Kinase 3"  
UVAPF Docket no. 00623-012 (Herr-Kinase3)  
PCT/US01/46803 Filed Nov. 9, 2001  
Pending U.S. Application no. 10/438,339 Filed May 9, 2003
24. Inventors: J.C. Herr, A. Mandal, M. Wolkowicz, and K. Klotz.  
Title: "Methods and Compositions for Modulating Fertility"  
UVAPF Docket no. 00121-03 (Herr-FSP95)  
PCT/US00/02675 Filed Feb. 1, 2000  
Pending U.S. Application no. US 09/890,709 Filed July 31, 2001

25. Inventors: J.C. Herr and P.P. Reddi  
Title: "An Insulator Element Having Enhancer-Blocking Properties"  
UVAPF Docket no. 00567-03 (Herr-Silence)  
PCT/US01/17110 filed on May 25, 2001  
Pending U.S. Application no. US 10/297,008 Filed Nov. 26, 2002
26. Inventors: J.C. Herr, P.E. Visconti, A. Wagenfield, M.A. Coppola, Z. Hao, and S. Vemuganti.  
Title: "TSSK4, A Human Testes Specific Serine/Threonine Kinase"  
UVAPF Docket no. 00927-02 (Herr-Kinase4)  
Pending U.S. Application no. 10/754,829 Filed Jan. 8, 2004

#### **D. Pending Foreign National Stage Patent Applications**

27. Inventors: J.C. Herr and R.M. Wright  
Title: "Human Intra-Acrosomal Sperm Antigen for Use in a Contraceptive Vaccine"  
UVAPF Docket no. 0215-11 (Herr-Sprmagp)  
PCT/US90/00978 Filed March 2, 1990  
Pending Foreign Application Nationalized in Japan
28. Inventors: J.C. Herr, A.B. Diekman, and E. Norton.  
Title: "Purified Sperm Surface Antigen, Monoclonal Antibody Therefor and Applications Therefor"  
UVAPF Docket nos. 216-11-14,15,16 (Herr-SprmAb1)  
PCT/US97/10813 Filed June 30, 1997  
Pending Foreign Applications Nationalized in Japan, Ukraine, Brazil, Norway, Republic of Korea, Canada, Mexico, China, and Hungary
29. Inventors: J.C. Herr, S. Naaby-Hansen, and C. Flickinger  
Title: "Method for the Production of Vaccines Against Cell Surface Proteins"  
UVAPF Docket no. 00217-05-12 (Herr-Vocprod)  
PCT/US98/02913 Filed Feb. 25, 1998  
Pending Foreign Applications Nationalized in Brazil, Canada, Hungary, Israel, Japan, Mexico, Poland, and the Republic of Korea
30. Inventors: J.C. Herr, S.C. Coonrod, and P. Wright.  
Title: "Egg-Specific Surface Proteins" filed Jan. 20, 2000.  
UVAPF Docket no. 00498-03-6 (Herr-MOP/CD9)  
PCT/US01/01718 Filed Jan 19, 2001  
Pending Foreign Applications Nationalized in Australia, Canada, European Patent Office, and Japan
31. Inventors: P.P. Reddi, C.J. Flickinger, and J.C. Herr  
Title: "Methods and Composition for Modulating Spermatogenesis"  
UVAPF Docket no. 00271-05-09 (Herr-Mouse)  
PCT/US99/14275 Filed June 25, 1999  
Pending Foreign Applications Nationalized in Israel, European Patent Office, Japan, Australia, and Canada
32. Inventors: J.C. Herr, A. Mandal, F. Jayes, J. Shetty, and M. Wolkowicz  
Title: "Sperm Specific Lysozyme Like Proteins"  
UVAPF Docket no. 00489-04-07 (Herr-Lysozym)  
PCT/US01/01716 Filed Jan. 19, 2001  
Pending Foreign Applications Nationalized in Australia, Canada, European Patent Office, and Japan
33. Inventors: J.C. Herr, S. Naaby-Hansen, A. Mandal, S. Beur, and M.J. Wolkowicz  
Title: "CBP86, a Sperm Specific Protein"

UVAPF Docket no. 00492-03-06 (Herr-CBP86)  
PCT/US01/01715 Filed Jan. 19, 2001  
Pending Foreign Applications Nationalized in Australia, Canada, European Patent Office, and Japan

34. Inventors: J.C. Herr, J. Shetty, M. Wolkowicz, F. Jayes, and Z. Hao  
Title: "Sperm Specific Proteins"  
UVAPF Docket no. 00497-03-06 (Herr-NIH)  
PCT/US01/01717 Filed Jan. 19, 2001  
Pending Foreign Applications Nationalized in Australia, Canada, European Patent Office, and Japan
35. Inventors: J.C. Herr, P. Visconti, and Z. Hao  
Title: "Human Testis Specific Serine/Threonine Kinase 1&2"  
UVAPF Docket no. 00623-04-06,-08 (Herr-Kinase)  
PCT/US01/46803 Filed Nov. 9, 2001  
Foreign Applications Nationalized in Australia, Israel, Japan, and the European Patent Office
36. Inventors: J.C. Herr, P. Visconti, Z. Hao, and G. Kopf.  
Title: "Human Testis Specific Serine/Threonine Kinase 3"  
UVAPF Docket no. 00623-09-11,-13 (Herr-Kinase3)  
PCT/US01/46803 Filed Nov. 9, 2001  
Foreign Applications Nationalized in Australia, Israel, Japan, and the European Patent Office
37. Inventors: J.C. Herr, A. Mandal, M. Wolkowicz, and K. Klotz.  
Title: "Methods and Compositions for Modulating Fertility"  
UVAPF Docket no. 00121-03 (Herr-FSP95)  
PCT/US00/02675 Filed Feb. 1, 2000  
Foreign Application Nationalized Australia (35868/00)

#### **E. Pending PCT Applications**

38. Inventors: J.C. Herr, M.B. Herrero, A. Mandal, and L.C. Digilio  
Title: "Sperm Specific Lysozyme-Like Proteins"  
UVAPF Docket no. 00857-02 (Herr-SLP.USE)  
PCT/US04/01240 Filed Jan. 16, 2004
39. Inventors: C.D. Allis, J.C. Herr, S.A. Coonrod, and Y. Wang  
Title: "ePAD, an Oocyte Specific Protein"  
UVAPF docket no. 00856-02 (Herr-ePAD)  
PCT/US04/00591 Filed Jan. 8, 2004
40. Inventors: J.C. Herr, P.E. Visconti, A. Wagenfield, M.A. Coppola, Z. Hao, and S. Vemuganti  
Title: "TSSK4, A Human Testes Specific Serine/Threonine Kinase"  
UVAPF Docket no. 00927-02 (Herr-Kinase4)  
PCT/US04/02531 Filed Aug. 5, 2004
41. Inventors: J.C. Herr and A. Mandal  
Title: "SpermCollect™, A Glans Compatible Single Unit Semen Collection and Storage Device, Kit, and Related Method Thereof"  
UVAPF Docket no. 00942-02 (Herr-Collect)  
PCT/US04/036916 Filed Nov. 5, 2004

42. Inventors: John C. Herr and Susan Sleight  
Title: "Bands5: A Human Testis Specific Protein"  
UVAPF Docket no. 00955-02 (Herr-Band5)  
PCT/US04/041440 Filed Dec. 8, 2004
43. Inventors: L. Gilmer, A. Mandal, M.J. Wolkowicz, K.L. Klotz, and J.C. Herr  
Title: "Compositions of Identifying Sperm for Forensic Applications"  
UVAPF Docket no. 00952-03 (Herr-Paint)  
PCT (no. to be assigned) Filed Feb. 7, 2005

#### **F. Pending Provisional Patent Applications**

44. Inventors: A. Mandal and J.C. Herr  
Title: "Active Recombinant Human Lysozyme"  
UVAPF Docket no. 00954-01 (Herr-ActiveLZ)  
Provisional Filed Feb. 20, 2004
45. Inventors: Y.H. Kim and J.C. Herr  
Title: "SFEC, A Sperm Flagellar Energy Carrier Protein"  
UVAPF Docket no. 00973-01 (Herr-SFEC)  
Provisional Filed March 17, 2004
46. Inventors: S.H. Lim, J.C. Herr, and A. Mandal  
Title: "Use of SLLP Proteins for Identification, Diagnosis, and Treatment of Cancer"  
UVAPF Docket no. 01000-01 (Herr-SLLPCAN)  
Provisional Filed June 22, 2004
47. Inventors: S.B. Sleight, J.C. Herr, and B. Xu  
Title: "Sperm Specific Raft Associated Proteins"  
UVAPF Docket no. 01035-01 (Herr-Band10)  
Provisional Filed Aug. 25, 2004
48. Inventors: J.C. Herr and Y.H. Kim  
Title: "Sperm Flagellar Energy Carrier Protein as a Contraceptive Target"  
UVAPF Docket no. 01045-01 (Herr-Polyol)  
Provisional Filed Sept. 30, 2004
49. Inventors: J.C. Herr, B. Xu, and Z. Hao  
Title: "Validation of TSSK Family Members and TSKS as Male Contraceptive Targets"  
UVAPF Docket no. 01048-01 (Herr-TSSK)  
Provisional Filed Sept. 30, 2004
50. Inventors: Y.H. Kim and J.C. Herr  
Title: "SFEC, A Sperm Flagellar Energy Carrier Protein"  
UVAPF Docket no. 00973-01 (Herr-SFEC)  
Provisional Filed March 17, 2004
51. Inventors: J.C. Herr, V.A. Westbrook, P.D. Schopeeee, and K.L. Klotz  
Title: "Use of SPAN-X for Identification, Diagnosis and Treatment of Fertility and Cancer Related Diseases and Disorders"  
UVAPF Docket no. 01059-01 (Herr-XAssay)  
Provisional Filed Nov. 5, 2004

52. Inventors: W. He and J.C. Herr  
Title: "Compositions and Methods for Novel ePAD Genes"  
UVAPF Docket no. 01063-01 (Herr-cdePAD)  
Provisional Filed Nov. 23, 2004
53. Inventors: W. He and J.C. Herr  
Title: "Contraceptive Vaccines for Dogs and Cats Based on Egg Membrane Antigens"  
UVAPF Docket no. 01065-01 (Herr-VetVaccine)  
Provisional Filed Nov. 23, 2004
54. Inventors: O. Chertihin and J.C. Herr  
Title: "Contraceptive Vaccines for Dogs and Cats Based on Egg Membrane Antigens"  
UVAPF Docket no. 01065-02 (Herr-Vet2)  
Provisional Filed Dec. 14, 2004

#### Other Patents

55. Inventors: D. Gerdt and J.C. Herr. "Fiber Optic Evanescent Wave Sensor for Immunoassay."  
US Patent #5,494,798, Granted Feb. 27, 1996.

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Invited Presentations at Universities, Federal Agencies, Corporations, and National Meetings

"Isolation of Sperm Surface Antigens," Developmental Biology Retreat, University of Washington, February 10, 1979, Lake Wilderness.

"Sperm Surface Antigens," E. M. Eddy and J. C. Herr, Gordon Research Conference on the Mammalian Genital Tract. July 7-11, 1980, Colby-Sawyer College, New London, NH.

"Dissection of the Mouse Sperm Surface Using Heterologous and Monoclonal Anti-sperm Antibodies," University of Minnesota, June 9, 1980.

"Molecular Dissection of the Mouse Sperm Surface with Monoclonal Antibodies," Bowman-Gray Medical School, February 1981.

"Human Hybridomas Constructed with Peripheral Blood Lymphocytes from Vasectomized Men" Joint Immunobiology Meeting. Harpers Ferry, W.Va., May 13, 1984.

"Monoclonal Antibodies - New Dimensions in Immunological Analysis" May 18, 1984, Eli Lilly Sponsored, St. Cloud, Minnesota Hospital Forum.

"Monoclonal Antibodies in Forensic Stain Characterization" FBI Academy, June 11, 1984.

"Monoclonal Antibodies to Seminal Fluid Specific Marker Protein MHS-5 and Serum Albumins" FBI Academy, Nov. 13-14, 1984.

"MHS-5 - a Monoclonal Antibody for Forensic Science" Endotronics, Minneapolis, Minnesota, May 17, 1985.

"Monoclonal Antibodies and Forensic Serology" Scotland Yard, London, England, August 19, 1985.

"ELISA Assay for Human Semen in Forensic Samples Employing Monoclonal Antibody MHS-5" FBI Headquarters, Washington, D.C. September 12, 1985.

"Monoclonal Antibody Based Assays for Identification of Human Blood and Semen" Workshop on Allotype Genetic Markers, American Academy of Forensic Sciences, New Orleans, February 14, 1986.

"A Monoclonal Antibody Probe for Rape Detection" Charlottesville, Rape Crisis Center, February 19, 1986.

- "Monoclonal Antibody Probes for Detection of Semen and Identification of Blood" October 17, 1986  
Food and Drug Administration, Silver Spring, Maryland, Office of Medical Devices.
- "Monoclonal Antibody, MHS-5 - A New Probe for Sexual Assault Evidence", Department of Biology,  
Virginia Commonwealth University, Richmond, VA. November 6, 1986.
- "Monoclonal Antibody for Detection of Semen and Identification of Blood". Crime Lab Directors, FBI  
Academy, Quantico, VA, November 13, 1986.
- "Application of Anatomy and Immunology in Criminology" Forum in Anatomy, May 11, 1987.  
American Association of Anatomy, Washington, D.C. Annual Meeting.
- "Seminal Vesicle Specific Antigen" October 8, 1987 University of New Mexico, Albuquerque, NM.
- "Monoclonal Antibodies to Cervical Mucus, Sperm Surface and Seminal Fluid". FBI Academy,  
Quantico, VA. February 11, 1988.
- "Update on Human Decidual Secretion and Differentiation Antigens of Human Spermatogenesis".  
Genentech, Inc., South San Francisco, CA. February 19, 1988.
- "Novel Antigens Involved in Human Semen Liquefaction and Spermatogenesis". University of Iowa,  
Iowa City, IA. February 26, 1988.
- "Monoclonal Antibody Probe for Novel Seminal Vesicle Specific Marker - New Diagnostic for  
Rape Detection". Igen, Inc., Rockville, MD. March 7, 1988.
- "Overview of FBI Contract Research at the University of Virginia". Invited Speaker for FSOPC  
Committee, May 3, 1988, FBI Academy.
- "Human Sperm Surface and Acrosomal Antigens Probed with Murine Monoclonal Antibodies".  
Invited Symposium Speaker, Symposium on Sperm Antigens in Reproduction, Am.  
Assoc. for Immunol. of Reproduction, Portland, ME. June 17, 1988.
- "Biochemical, Morphological and Genetic Characterization of SP-10 an Intra-Acrosomal Human  
Sperm Protein" The Population Council, The Rockefeller Univ., New York, N.Y. March 16,  
1989.
- "Molecular Biology of Human Spermatogenesis - Characterization of the intra-acrosomal  
antigen SP-10." Dept. Anatomy, University of Iowa, May 26, 1989.
- "Molecular Biology of Human Spermatogenesis - Characterization of the intra-acrosomal antigen SP-  
10 and its encoding gene." Dept. Anatomy, Univ. of Wisconsin-Madison, May 30, 1989.
- "The Intra-acrosomal antigen SP-10" 4th International Congress of Reproductive Immunology,  
Kiel, Germany, July, 1989.
- "Contraceptive Vaccine Candidate SP-10" Ortho Pharmaceuticals, Raritan, NJ, August 11, 1989.

- "A Marker for Sperm Heads in Sexual Assault Evidence". Lifecodes Corp, Valhalla, NY, August 22, 1989.
- "Monoclonal Antibody MHS-10 and its Cognate Antigen SP-10" CONRAD Symposium of Immunocontraception, Bariloche, Argentina, November, 1989.
- "Biochemical and Morphological Characterization of SP-10" National Institute of Immunology, New Delhi, India, March 14, 1990
- "Biochemical and Morphological Characterization of the Intra-acrosomal antigen SP-10" May 11. 1990 National Institute of Environmental Health Sciences, Research Triangle, N.C.
- "A Differentiation Antigen of Human Spermatogenesis" Gordon Research Conference, Mammalian Genital Tract, Wolfboro, NH July 11, 1990.
- "Development of A Sperm Based Contraceptive Vaccine" Food and Drug Administration, Rockville, MD, Jan 29, 1991.
- "Contraceptive Vaccine Candidate SP-10 Associated with Human Sperm Acrosomal Membranes" American Association for the Advancement of Science, Washington, D.C., Feb 15, 1991.
- "Biochemical, Morphological and Immunogenicity Studies of a Sperm Based Contraceptive Vaccine for Women" Louisiana State University, New Orleans, LA. March 18, 1991.
- "Organization and Direction of the Center for Recombinant Gamete Contraceptive Vaccinogens" National Institutes of Health, Lister Hall, Washington, D.C., Feb. 27, 1992.
- "Intra-Acrosomal Contraceptive Vaccine Immunogen SP-10 in Man, Macaque and Baboon" Serono Symposium, Beaverton, OR. May 31, 1992.
- "Update on Sperm Antigen SP-10" 20th Anniversary Symposium of World Health Organization Special Program of Research, Development and Research Training in Human Reproduction. Moscow, Russia, June 17, 1992.
- "Cell and Molecular Biology of the Intra-acrosomal Antigen SP-10" Gordon Conference on Mammalian Genital Tract, Plymouth State College, Plymouth, NH, July 9, 1992.
- "Antibodies to Sperm Protein SP-10 in Infertile Couples; The Expression of Pure Recombinant SP-10 to Serve as Assay Target" U.S.A.I.D. Contraceptive Development and Research Initiative Working Group. Washington, DC, September 17, 1992.
- "Updates in Immunocontraception" Armed Forces District American College of Obstetrics and Gynecology, November 2, 1992, Norfolk, VA.

- "Molecular Approaches to Gamete Surface Antigens" December 2, 1992, Calcutta, India.
- "Biochemical, Morphological and Genetic Characterization of the Intra-Acrosomal Antigen SP-10" December 4, 1992, Institute of Chemical Biology, Calcutta, India.
- "Immunogenicity of Recombinant SP-10 in Female Baboons" December 9, 1992, Symposium on Recombinant and Synthetic Vaccines, Delhi, India.
- "Biochemical, Morphological, and Genetic Characterization of the Intra-Acrosomal Sperm Protein SP-10: A Human Contraceptive Vaccine Candidate Currently Undergoing Testing in Baboons" March 4, 1993, Oregon Regional Primate Research Center, Beaverton, OR.
- "Sperm Surface Antigens as Targets for Immunocontraception" April 17, 1993, 18th Annual Meeting American Society of Andrology, Tampa, FL.
- "Biochemical, Morphological and Genetic Characterization of Intra-Acrosomal Protein SP-10" May 11, 1993, Department of Cell Biology and Anatomy, University of North Carolina, Chapel Hill, NC.
- "Prospects for Contraceptive Vaccines Based on Sperm-Surface Immunogens: May 18, 1993, Grand Rounds Department Obstetrics and Gynecology, Oregon Health Sciences University, Portland, OR.
- "Intra-Acrosomal Protein SP-10: A Contraceptive Vaccine Candidate" May 24, 1993. Reproductive Immunology Mini-Symposium, American Association for Immunology, Denver, CO.
- "Immunologic Aspects and Potentials in Contraception" June 5, 1993, Thornton Conference, Omni Hotel, Charlottesville, VA.
- "Immunogenicity of SP-10 Fusion Proteins in Female Baboons" June 18, 1993, Sixth Annual Mid-Atlantic Reproductive Biology Meeting, Johns Hopkins University, Baltimore, MD.
- "The Immunobiological Effects of Vasectomy and Vasovasostomy in the Rat Model" August 29, 1993, Serona Symposium on Immunobiology of Reproduction, Boston, MA.
- "Results of Baboon Immunogenicity Trials Comparing GT-SP-10 Fusion Protein from pGEX with SP-10 Produced in pET" October 29, 1993, NIH Contraceptive Development Centers Annual Meeting, Wintergreen, VA.
- "Update on Contraceptive Vaccine Immunogen - SP-10" December 11, 1993, Japanese Society for Reproductive Immunology, Nara, Japan.
- "Microheterogeneity of the Intra-acrosomal Protein SP-10 is due to Alternative Splicing and Proteolytic Processing" February 9, 1994, Boden Conference, Thredbo, Australia.
- "Sperm Specific Intra-Acrosomal Antigen SP-10" May 12, 1994, Endocrinology and Reproductive Biology Seminar Series, The Population Council, The Rockefeller University, New York, NY.



- "cDNA Cloning in Progress: Sperm Antigens Recognized by Auto and Iso Anti-Sperm Antibodies" June 3, 1994, Seventh Mid-Atlantic Reproductive Biology Meeting, Georgetown University, Washington, DC.
- "Candidate Vaccinogens for a Sperm Based Immunocontraceptive" September 30, 1994, Zonagen, Inc., Woodlands, TX
- "Overview of Contraceptive Vaccine Development in the Center for Recombinant Gamete Contraceptive Vaccinogens" December 8, 1994, Institute of Medicine, National Academy of Science, Washington, DC
- "Human Sperm Surface Proteins as Contraceptive Vaccinogens" May 2, 1995, Department of Anatomy and Cell Biology, University of Iowa
- "Biochemical, Morphological and Genetic Characterization of the Intra-Acrosomal Protein SP-10, a Contraceptive Vaccine Candidate" May 4, 1995, Seminar Series in Cell Biology, Developmental Biology and Neuroscience, University of Kansas, Kansas City
- "A Tale of Sperm, Sperm Antigens and Infertility" May 5, 1995, Medical Histology and Cell Biology, University of Kansas Medical School
- "Advances in Immunocontraception," June 5, 1995, National Advisory Committee on Child Health and Human Development, National Academy of Sciences, Washington, D.C.
- "Immunizing with Sperm Antigens to Prevent Fertilization," July 8, 1995, SSR Workshop on the Immunology of Implantation, Davis, California.
- "The Use of Acrosomal Antigens as Contraceptive Immunogens: Studies on the Intra-acrosomal Antigen SP-10," International Symposium on the Human Sperm Acrosome Reaction, September 9, 1995, Collioure, France
- "Recent Advances on the Path to a Contraceptive Vaccine," 15th World Congress on Fertility and Sterility, September 20, 1995, Montpellier, France
- "Morphological, Biochemical, and Genetic Characterization of the Intra-acrosomal Protein SP-10," December 5, 1995, Department Zoology, Ain Shams University, Cairo, Egypt.
- "The Biotechnology of Contraceptive Vaccine Development," December 9, 1995, Ain Shams University, Cairo, Egypt.
- "The Path to Contraceptive Vaccine Development," December 11, 1995, Al-Azhar University, Cairo, Egypt.
- "Development of a Home-Sperm-Test," February 2, 1996, Chefaro, Oss, The Netherlands.

- "Strategies in the Development of a Sperm Based Contraceptive Vaccine," February 3, 1996, Organon, N.V., Oss, The Netherlands.
- "Steps on the Pathway to a Contraceptive Vaccine," March 22, 1996, Finnish Andrology Society Plenary Lecture, Turku, Finland.
- "The Development of Sperm Antigen Based Contraceptive Vaccines," March 25, 1996, Leiras, N.V. Turku, Finland.
- "Sperm Antigens in Infertility and Contraception," June 1, 1996, Clinical Immunology Society, New Orleans, LA.
- "Contraceptive Vaccine Development," October 11, 1996, Food and Drug Administration, Rockville, MD.
- "The Two Cultures: The Language of Science and the Language of Venture Capital, Refining Scientific Ideas for the Venture Community," Conference on Opportunities for Industrial Collaboration in Contraceptive Research, Family Health International, November 7, 1996, Durham, NC.
- "Multidisciplinary Training in Contraceptive Vaccine Development for Indian Postdocs," May 20, 1997, Advisory Board Fogarty International Center, National Institutes of Health, Washington, DC.
- "Strategies for the Development of a Sperm Antigen Based Contraceptive Vaccine," June 24, 1997, European Society of Human Reproduction and Embryology, Edinburgh, Scotland.
- "Discovery and Characterization of Sperm Contraceptive Vaccinogens," July 8, 1997, Vaccines Beyond 2000, Gold Coast, Queensland, Australia.
- "Strategies for Identification of Cell Surface Vaccinogens," September 30, 1997, First International Conference on Experimental and Clinical Reproductive Immunobiology, Charlottesville, VA.
- "A Strategy for Identification of Sperm Surface Vaccinogens," November 16, 1997, NIH Joint Centers' Meeting, Davis, CA.
- "Contraceptive Products Under Development in the Center for Recombinant Gamete Contraceptive Vaccinogens," January 8, 1998, presented to NIH Advisory Council on Contraceptive Clinical Network.
- "Home Sperm Test" Virginia Biotechnology Association, Richmond, VA. Biotechnology Park, March 23, 1998.
- "A Strategy for Identification and Cloning of Novel Sperm Surface Immunogens" Guest Symposium of Amer. Assoc. Immunologists, San Francisco, Calif. April 19, 1998.

- “A Strategy for Identification of Sperm Immunogenes Relevant to Infertility”. Symposium on Clinical Implications in Reproductive Biology, Woods Hole, Mass, June 10, 1998.
- “Identification of Sperm Specific-Marker Proteins for use in Sperm Detection and Quantification.” Virginia Tech Biotechnology Center, Blacksburg, VA. April 23, 1999.
- “Preparations for a Human Trial on LDHC-4: TT Chimeric Peptide Vaccine: Rationale for Trial and Response of FDA to IND” Schering AG, Berlin, FRG. May 27, 1999
- “Oolemmal Vaccine Development: Oolemmal Proteomics” Schering AG, Berlin FRG May 28, 1999.
- “An Immunochromatographic Card for Detecting and Quantifying Sperm”, Frontiers in Reproduction, Marine Biological Laboratories, Woods Hole, MASS. June 10, 1999
- “2-D Sperm Proteomics” Frontiers in Reproduction, Marine Biological Laboratories, Woods Hole, MA. June 11, 1999
- “Progress in Developing an Immunochromatographic Device for Sperm Detection” Association of Medical Laboratory Immunologists, Bethesda, MD. July 10, 1999
- “Cooperative International Research and Capacity Building in Reproduction and Contraception” Workshop on Global Research on Women and Children’s Health, NICHD, Bethesda, MD. September 14, 1999
- “Design of the Home Sperm Test” Workshop on Improving Acceptability Research, NICHD, Bethesda, MD. October 25, 1999.
- “Assorted Arcana of Sperm Cytoarchitecture” University of Pennsylvania, Center for Research on Reproduction and Women’s Health. October 27, 1999.
- “Sperm Binding Magnetic Bead Employing Sperm Agglutination Antigen 1 [SAGA-1]” Future Directions Session, Fifth Annual CODIS User’s Group Meeting, US Department of Justice, Federal Bureau of Investigation, Arlington, VA. November 19, 1999.
- “Sperm Binding Magnetic Bead Employing Sperm Agglutination Antigen 1 [SAGA-1]” Cellmark, a division of Astra Zeneca, Oxford, England. November 22, 1999.
- “RASA: A Recombinant Anti-Sperm Antibody Directed Against the Sperm Glycoform of CD52”. “Pre-Clinical Topical Microbiocides Workshop” NIH, Bethesda, MD. January 13, 2000.
- “Overview of the Program: The Contraceptive Vaccine Search for Testis Specific Genes and Proteins Opens Other Contraceptive Leads” Schering AG, Berlin, FRG. January 26-28, 2000.
- “Calcium binding to CBP86, a novel testis-specific calcium-binding protein localized in the principal piece of human sperm, is regulated by phosphorylation during capacitation”. Schering AG, Berlin, FRG. January 26-28, 2000.

- “Update on the LDH-C4 Contraceptive Vaccine IND” Schering AG, Berlin, FRG. January 26-28, 2000.
- “A Sperm Binding Bead for Forensic-DNA Analysis” Schering AG, Berlin, FRG, January 26-28, 2000.
- “New Approaches to Contraception” Executive Council Planned Parenthood of the Blue Ridge, October 2, 2000.
- “CBP86, a novel testis-specific calcium binding protein localized in the tail of human sperm undergoes phosphorylation and oligomerization during capacitation” International Congress on Fertilization, Embryo Development and Implantation. New Delhi, India, November 6, 2000.
- “Discovery Driven Translational Research in Sperm Proteomics and Genomics” Department of Molecular Reproduction, Development and Genetics, and the Department of Biochemistry, Indian Institute of Science, Bangalore, India, November 10, 2000.
- “Sperm Proteomics and the Discovery of Contraceptive Targets” Schering AG, Berlin, Germany, November 14, 2000
- “Span-X as a Cancer-Testis Marker” Schering AG, Berlin, Germany, November 14, 2000
- “Proteomic Approaches to Identifying Contraceptive Targets” Second International Conference on Experimental and Clinical Reproductive Immunobiology, Amsterdam, The Netherlands, November 16, 2000.
- “From Basic Sperm Biology to Commercialization of a Diagnostic Device: Biotechnology Underlying Sperm Check I, an Immunochromatographic Card for Detecting Low Numbers of Sperm” The Burroughs Welcome Lecture, University of Guelph, Ontario, January 30, 2001.
- “Commercializing Academic Research Through Startup Companies” University of Guelph’s Business Development Office, January 30, 2001.
- “The Development of Recombinant Miniantibodies as Targeting Vectors: Sperm Agglutination Antigen 1: Looking Toward a New Generation of Spermicidal Agents” Department Biomedical Sciences, University of Guelph, Ontario, January 31, 2001.
- “Proteomics: Discovery of Contraceptive Vaccines in the Post-Genomic Era.” Department of Biomedical Sciences, University of Guelph, Ontario, February 1, 2001.
- “Discovery of a Unique Sperm Surface Molecule - SAGA-1, and its use in Forensic Science” Randolph-Macon College, April 7, 2001.
- “A Multi-Determinant Contraceptive Vaccine Based Upon Testis-Specific Human Sperm Head Antigens: Immunogenicity and Efficacy Trials in Monkeys” Schering, AG, May 8, 2001.
- “Sperm Cell Selection System for Forensic DNA Analysis of Male Component” National Institute of Justice, Washington, D.C., June 7, 2001.

- “Sperm Proteomics and the Discovery of Testis-Specific Contraceptive Targets” American Society for Immunology of Reproduction 21st Annual Meeting, Chicago, IL, June 10, 2001.
- “Sperm Proteomics and the Discovery of Testis-Specific Contraceptive Targets” Frontiers in Reproduction Symposium, Cambridge, MA, June 30, 2001.
- “Sperm Proteomics and the Discovery of Testis-Specific Contraceptive Targets” VIII Congress of the International Society of Reproductive Immunology, Opatia, Croatia, July 6, 2001.
- “Sperm Proteomics and the Discovery of Testis-Specific Contraceptive Targets” The Ludwig Institute, New York, N.Y. December 4, 2001.
- “Sperm Proteomics and the Discovery of Contraceptive Targets” Dept. Anatomy and Cell Biology, Univ. of Iowa, May 30, 2002.
- “Sperm Proteomics and the Discovery of Targets for Contraception and Cancer” Plenary Session, XX11nd Annual Meeting American Society of Reproductive Immunology. Chicago, Ill. June 6, 2002.
- “The Biotechnology Underlying Sperm Immunodiagnostics” National Institute of Health John F. Fogarty International Center, Washington, D.C., June 11, 2002.
- “Sperm Cell Selection System for Forensic DNA analysis of the Male Component” Third Annual DNA Grantees Conference, National Institute of Justice, Washington, D.C., June 24, 2002.
- “Defining the Sperm Proteome” Gordon Research Conference on Gametogenesis and Embryogenesis. Connecticut College, July 4, 2002.
- “Contraceptive Vaccines and Spermistatic Mini-antibodies Targeting Sperm Surface Sugars” 2nd Annual Advances in Contraceptive Health Symposium” Boston, MA., July 20, 2002.
- “The Sperm Check Immunodiagnostic” Princeton Bio Medi Tech, Princeton, N.J., September 17, 2002.
- “A Case Study in the Transfer of University Intellectual Property to a Biotechnology Start-up” General Assembly Building, Joint Commission on Technology and Science, Richmond, VA, September 25, 2002.
- “Specification of an Equitorial Segment Domain During Early Acrosomal Biogenesis—A Susceptible Biological Process For Targeting A Male Contraceptive?” Schering AG, Berlin, Germany, December 6, 2002.
- “Equitorial Segment Protein and Acrosomal Biogenesis”, Dept. of Biochemistry, Albert Einstein College of Medicine, Yeshiva University, Bronx, NY., May 6, 2003.
- “Immunogenicity of a pentavalent recombinant subunit anti-acrosomal vaccine in monkeys.” Hippokration Congress on Reproductive Immunology, June 4, 2003, Rhodes, Greece.

- “Novel Acrosomal Matrix Proteins ESP and SAMP 14: Roles in fertilization and Acrosome Biogenesis.” Georgetown University, Dept. of Cell Biology, June 12, 2003.
- “Sperm Cell Selection System for Forensic DNA Analysis of the Male Component” Fourth Annual DNA Grantees Workshop, Natl. Institute of Justice, Washington, DC. June 25, 2003.
- “The Biotechnology Underlying Sperm Immunodiagnosis” Syntron Bio Research Inc., Carlsbad, CA, July 2, 2003
- “Proteomics and the Discovery of Contraceptive Drug and Vaccine Targets” Institute of Medicine, National Academy of Sciences, New Frontiers in Contraceptive Research International Symposium, Washington, DC. July 15, 2003.
- “ContraVac: Anatomy of a start-up” Emerging Technology Partners, Rockville, MD Sept. 25, 2003
- “Mining the Sperm Proteome for Contraceptive Targets” Indo-US Workshop on Male Contraceptive Research and the Role of Men in Reproductive Health. Oct. 20, 2003, National Institute of Immunology, New Delhi, India.
- “Mining the Sperm Proteome for Uncharted Regions of the Human Genome” Center for Cell and Molecular Biology, October 24, 2003 Hyderabad, India.
- “Mining the Sperm Proteome for Uncharted Regions of the Human Genome” Center for Research in Reproductive Health, October 27, 2003 Mumbai, India.
- “ePAD, an Egg Specific Peptidyl Arginine De-iminase is the Most Abundant Protein in the Ovulated Mammalian Egg and Represents a New Contraceptive Target” Center for Research in Reproductive Health, October 28, 2003 Mumbai, India.
- “Patterns of SPAN-X Gene Expression in Human Spermiogenesis, Melanomas and During the Cell Cycle” Laboratory of Biosystems & Cancer, Center for Cancer Research, National Cancer Institute, Bethesda, MD. December 2, 2003
- “Rapid Tests for Post Vasectomy Sperm Testing” Expert Consultation on Vasectomy, Family Health International/Engender Health, Washington DC, December 3, 2003
- “Opportunities for Collaboration: Acceptability and Utilization of Rapid Tests for Sperm Detection” Joint Maternal and Child Health and Population and Health Centers Network Meeting, NIH Fogarty International Centers, Washington, DC, December 5, 2003
- “Update of Human ePAD Intellectual Property Issues” Schering AG, Berlin, Germany December 8, 2003
- “Update on Performance of Rapid Tests for Sperm Detection” Schering AG, Berlin, Germany, December 8, 2003

- “Patterns of SPAN-X Gene Expression in Human Spermiogenesis, Melanomas and During the Cell Cycle” Schering, AG, Berlin, Germany December 8, 2003
- “Intelligent Spermicides: Spermistatic Bivalent Mini-antibodies Targeting Sperm Surface Sugars” Schering AG, Berlin Germany December 9, 2003
- “Diagnostic and Therapeutic Products Emerging from the Human Sperm Proteome.” Jan. 14, 2004 Repromedix Inc. Boston, Mass.
- “Mining the Sperm Proteome for Uncharted Regions of the Human Genome.” Dept. of Biomedical Sciences , College of Veterinary Medicine, Cornell University, Ithaca, N.Y. Feb. 3, 2004
- “ContraVac: Technology Transfer and Alternative Careers” Johnson School of Management and the Physiology Graduate Student Club, Cornell University, Ithaca, N.Y. Feb. 3, 2004
- “ContraVac: Products, People, and Purpose”. Piedmont Angel Network, Greensboro, N.C. March 9, 2004
- “Mining the Sperm Proteome for Uncharted Regions of of the Human Genome” The Raymond O. Berry Memorial Lecture, Dept. Reproductive Physiology, Texas A&M University, April 2, 2004
- “The Technology Underlying Sperm Check” Carrilion Biomedical Institute, Ronoake, VA April 8, 2004
- “Mining the Sperm Proteome for Uncharted Regions of the Human Genome” FASEB Symposium Control Mechanisms in Mol. Reproduction, April 21, 2004, Washington, DC
- “Mining the Sperm Proteome for Uncharted Regions of the Human Genome”. Dept. Pharmacology, Rush University, Medical Center, Chicago, May 12, 2004
- “Interdisciplinary Postdoctoral Training in Reproductive Biology and Contraceptive Development for Asian Fellows: The Evolving Experiment”. Fogarty International Center, NIH campus, Washington, DC, May 17, 2004.
- “Reproductive Biology and Physiology Relevant to Urology”. American Urological Association, June 7, 2004. Basic Sciences for Urology residents Course.
- “Proteomics and the Discovery of Companion Animal Contraceptive Drug and Vaccine Targets in the Sperm and Egg”. Alliance for Contraception in Cats and Dogs, Breckenridge, Colorado. June 27, 2004
- “SpermPaints: Fluorescent Monoclonal Antibody Probes for Sperm Identification”. 5<sup>th</sup> Annual DNA Grantees Workshop, National Institute of Justice, Washington, DC, June 29, 2004.
- “ContraVac: Anatomy of a Start-up”, Center for Innovative Technology, SBIR Phase II Competition, Washington, DC September 15, 2004.

“Proteomics of Isolated Human Sperm Fibrous Sheath: Machinery of Glycolysis and a Novel Sperm Flagellar Energy Carrier Protein” The Future of Male Contraception, Seattle, WA, October 1, 2004.

“SpermCheck® Contraception: An Immunochromatographic Cassette for Monitoring Male Contraceptive Efficacy.” Virginia’s 10<sup>th</sup> Annual SBIR Conference, Crystal City, VA, October 13-14, 2004.

“The Role Equatorial Segment Protein in Acrosome Biogenesis” IX International Congress of Reproductive Immunology. Hakone, Japan, October 15, 2004

“SpermPaints and Compliance Testing” Schering Video Conference, December 18, 2004.

“The Role Equatorial Segment Protein in Acrosome Biogenesis.” Invited Speaker, Advances and Challenges in Reproductive Health in the PostGenomic Era, Mumbai, India, Jan 13, 2005.

“SpermPaints: Genomics and Proteomics of Sperm Differentiation Biomarkers” Invited Speaker: Bode Technologies Group, Springfield, VA. March 9, 2005

“Equatorial Segment Protein and Acrosome Biogenesis” Invited Speaker: Cell Biology of Fertilization, American Society of Andrology, April 4, 2005. Seattle, WA.

“Reproductive Biology and Physiology Relevant to Urology”. American Urological Association, June 6, 2005. Basic Sciences for Urology Residents Course.

“Proteomics of Isolated Human Fibrous Sheath: Machinery of Glycolysis and a Novel Sperm Flagellar Energy Carrier Protein” Invited Speaker: 25<sup>th</sup> Annual Meeting of the American Society of Reproductive Immunology, Providence, RI, June 17, 2005

“SpermPaints: Fluorescent Monoclonal Antibody Proves to Sperm Differentiation Antigens- Application in Sexual Assault Analysis” Invited Speaker: Sixth Annual DNA Grantees Workshop, US Department of Justice, National Institute of Justice, Washington, DC, June 27, 2005

“Update on the SPAN-XA/D Genes: Role in Human Spermiogenesis” Invited Speaker: National Cancer Institute, Laboratory for Biosystems and Cancer, NIH Campus, Washington, DC, July 28, 2005.

“Fruits of Indo-US Collaboration Between NII-UVA. AIM: To Identify AKAP-3 Interacting Proteins” NIH Indo-US Program on Contraception and Reproductive Health, Rockville, MD. August 22, 2005.

“25 Years After Passage Has the Promise of the Bahy-Dole Act Been Fulfilled?” NIH Indo-US Program on Contraception and Reproductive Health, Rockville, MD. August 24, 2005.

“The SpermPaint Probes for Sexual Assault Analyses” Nassau County District Attorney, Minneola, NY October 10, 2005.



"Analysis of Sexual Assault Smears in the Theresa Fusco Murder", Nassau County District Attorney, Minneola, NY November 1, 2005.

"A Role for the Equatorial Segment in Acrosome Morphogenesis" The Feinstein Institute for Medical Research, North Shore Long Island Jewish Health System, Manhasset, NY November 8, 2005.

#### Seminars Presented at UVA

"Dissection of the Mouse Sperm Surface with Heterologous Antiserum and Monoclonal Isoantibodies", Internal Medicine, Immunology Conference Group, March 31, 1982.

"Sperm Cell Surfaces," Cell Biology Colloquium, Fall 1981.

"Monoclonal Antibodies to the Mouse Sperm Surface," Immunology Council Faculty Seminar, June 22, 1982.

"Human Hybridomas," Hybridoma Research Group (R.L. Rhee), November 9, 1983.

"Human Hybridomas Constructed Post Vasectomy," Anatomy - April 1984.

"Monoclonal Antibodies for Use in Analysis of Sexual Assault Evidence". December 5, 1984. Immunology Conference Group.

"Monoclonal Antibodies for Sexual Assault Analysis". Department of Biochemistry, March 21, 1985.

"A Novel Sperm Coating Antigen Originating in the Seminal Vesicle" February 1985. Reproductive Sciences.

"Monoclonal Antibodies: Careers in Biotechnology" April 19, 1985. Biology Association, Gilmer Hall.

"Patenting of Hybridomas for Forensic Markers" November 2, 1985. Board of Directors, University of Virginia Patents Foundation.

"Seminal Vesicle Specific Monoclonal Antibody: A Novel Rape Detection Probe" November 20, 1985. Immunology Conference Group.

"Monoclonal Antibodies in Forensic Detection" September 18, 1987 Clinical Pharmacology/ Toxicology Interdisciplinary Conference; Department of Pathology.

"Monoclonal Antibodies-Strategies and Applications to the Development of a Contraceptive Vaccine" September 22, 1987 Infectious Disease Lecture in Basic Science.

"New Forensic Methods for Identifying Collectable Evidence" October 20, 1987 American Society for Industrial Security (Blue Ridge Chapter).

- "A Novel Antigen Within the Human Sperm Acrosome: A Potential Contraceptive Vaccine Immunogen" Dept. Anat. Cell Biol. April 20, 1989.
- "Molecular Biology of Human Spermatogenesis" Dept. Rheumatology - June 28, 1989.
- "Biochemical and Immunogenicity Studies of a Recombinant Human Sperm Contraceptive Vaccine" December 5, 1990; Immunology Conference Group
- "SP-10: A Recombinant Sperm Immunogen in Contraceptive Vaccine Development", Feb. 4, 1992, Department of Pathology
- "Restricted Domains of Sperm Antigens Recognized by Monoclonal Antibodies" February 26, 1992, Immunology Conference Group
- "Mission of the Contraceptive Vaccine Center" March 28, 1992, University of Virginia Board of Visitors
- "Dissecting the Sperm Surface: Applications for Contraception" June 30, 1992, Summer Research Internship Program (MARC/MAAP)
- "Sperm Surface Molecules as Contraceptive Vaccine Components" November 17, 1992, Sigma Xi Luncheon Seminar Series, Minor Hall
- "Immunologic Aspects and Potentials in Contraception" June 5, 1993, The W. Norman Thornton, Jr. Symposium
- "Dissecting the Sperm Surface: Applications for Contraception" July 13, 1993, Summer Research Internship Program (MARC/MAAP)
- "Contraceptive Vaccines", July 18, 1994, Summer Research Internship Program (MARC/MAAP)
- "Technology Transfer: Are Monoclonal Antibodies to the Sperm Antigen Useful for a Commercial Sperm Diagnostic?" November 20, 1994, Immunology Conference Group
- "Steps on the Pathway to Developing a Contraceptive Vaccine", May 15, 1995, American Gynecological Club, Department Ob/Gyn
- "Dissecting the Human Sperm Surface: Application for Contraceptive Vaccine Development," June 20, 1995, Medical Academic Advancement Program.
- "Keeping It At Home: The Anatomy of a Start Up," Jan. 20, 1996, Faculty Retreat, The Greenbrier, West Virginia.
- "Translational Research Panel," Nov. 15, 1996, Dept. Biomedical Engineering
- "The Quest for a Contraceptive Vaccine," Jan. 24, 1997, Medical Alumni Council

- "The Quest for a Contraceptive Vaccine: Bridging Basic and Applied Science," Feb. 12, 1997, Medical Center Hour
- "ContraVac: Anatomy of a Start Up," April 19, 1997, The Acadapreneures Forum, The Darden School
- "Strategies in the Development of a Sperm Antigen Based Contraceptive Vaccine," July 16, 1997, Medical Academic Enhancement Program.
- "Technology Transfer in Progress at the University of Virginia," October 29, 1997, Dept. Mechanical, Aerospace and Nuclear Engineering.
- "Forbidden Knowledge," November 19, 1997, Medical Center Hour.
- "Fruits of Leadership in Research- Contraceptive Vaccine Development" Jan. 20, 1998, UVA Medical Alumni Advisory Meeting, Pentagon City, Virginia.
- "Translating Basic Discoveries Into Useful Products within Academe" Cardiology Grand Rounds, May 5, 1998
- "The Home Sperm Test" SRIP Luncheon, June 19, 1998.
- "The Quest for a Contraceptive Vaccine" Blue Ridge Chapter of Planned Parenthood. October 12, 1998
- "Strategies for Identification of Novel Sperm Surface Proteins" Center for Research in Reproduction Enrichment Program Seminar. December 3, 1998
- "The Science and Clinical Uses of Spermcheck: An Immunodiagnostic for Detecting and Measuring Sperm" Molecular Medicine Rounds. May 25, 1999
- "Oolemma Proteomics: Egg Surface Antigens Important for Fertilization and Contraception" Infectious Disease Faculty Research Forum. September 8, 1999
- "Structure of a University Based Biotechnology Company" 2nd Conference on the Development of Technology in Medicine in Virginia, Omni Hotel, Sponsor; Dept. Biomedical Engineering. November 1, 1999
- "The Biotechnology Underlying Sperm Immunodiagnostics" Piedmont Virginia Community College's Introduction to Biotechnology Class-Biotechnology Center, 327 W. Main Street, Charlottesville, VA. November 16, 1999, April 5, 2000
- "Molecular Events Associated with Human Sperm Capacitation: Oligomerization and Phosphorylation of Calcium Binding Protein 86 [CBP86]" Cell Biology Retreat, September 16, 2000
- "Sperm Proteomics" Biotechnology Training Program, October 23, 2000

- “Discovery Driven Translational Research in Sperm Proteomics and Genomics: Venturing Beyond the Breakers when the Wind is Strong. Bernie B. Carter Center for Immunology Research, October 25, 2000.
- “The Biotechnology Underlying SpermCheck: From Idea to Product” Symposium on Patents and Intellectual Property, Jordan Hall Conference Center, February 6, 2001.
- “Sperm Proteomics and the Discovery of Targets for Contraceptive” Wintergreen, Immunology Retreat, June 1, 2001.
- “Issues in Intellectual Property Management” Molecular Medicine Round Table, May 1, 2002.
- “Innovation and Entrepreneurship” Molecular Medicine Round Table, November 14, 2002.
- “Intra-cytoplasmic Sperm Injection [ICSI]: A Grand Experiment in Reverse Eugenics” Critical Human Survival Issue, Foruming Dept. of Anthropology [UNK-45-1]. November 14, 2002.
- “Specification of an Equatorial Segment Domain During Early Acrosomal Biogenesis and Insights into the Ancestral Gene Program of Spermiogenesis”, Dept. of Biochemistry, November 21, 2002.
- “Acadapreneurship: Combining the Academic and the Entrepreneurial, A Case Study in the Transfer of University Intellectual Property to a Biotechnology Start-up.” Alternative Careers in Science Symposium, Feb. 26, 2003 sponsored by: The Beirne B. Carter Center for Immunology R, The Cardiovascular Research Center, and the Graduate Programs Office – School of Medicine.
- “The Roots of Acadapreneurship: Discovery, Invention, and Innovation” Workshop on Relations with Industry, March 10, 2003, Research Week, Undergraduate Research Network.
- “Equatorial Segment Protein and Acrosome Biogenesis” MARC Program, June 26, 2003.
- “The Biotechnology Underlying Immunodiagnostics for Sperm.” Aug. 4, 2003 Center for Innovative Technology.
- “The Biotechnology Underlying Sperm Check<sup>®</sup>” Sept. 15, 2003 Virginia National Bank.
- “Mining the Sperm Proteome for Uncharted Regions of the Human Genome.” Sept. 24, 2003 Dept. of Pathology
- “Anatomy of a U.VA Biotechnology Start-Up”, December 18, 2003. Carillion BioMedical Institute, Site Visit
- “SpermPaints for Forensic Science”, The John Steve Catilo Memorial Lecture, Univ. of Virginia, October 30, 2004.

“Testis-Specific Biomarkers of Sperm: The Story Behind SpermCheck and SpermPaints” November 6, 2004 83<sup>rd</sup> Annual Meeting of the Clinical Society of Genitourinary Surgeons, Department of Urology

“SpermPaints: Fluorescent Monoclonal Antibody Probes to Sperm Differentiation Antigens—Applications in Sexual Assault Analysis and Post-Coital Testing” Urology Conference, November 10, 2004.

“Cancer-Testis Antigens, The SPAN-X Gene in Human Spermiogenesis, HPCX, TGCT1, Melanomas and the Cell Cycle.” Urology Conference, February 16, 2005.

“Cancer-Testis Antigens, The SPAN-X Gene in Human Spermiogenesis, HPCX, TGCT1, Melanomas and the Cell Cycle.” Human Cancer Immunotherapy Conference, Feb 22, 2005

#### Research Activities Related to University-Industrial Relationships [Translational Research]

Endotronics In 1983 Dr. Herr established a cooperating venture between the University of Virginia and Endotronics, Inc. of Minneapolis, Minn. This resulted in a donation of a \$130,000 Acusyst 1501 instrument and a Mini Micro Chamber device to the University. These systems are perfusion devices for cell culture, esp. of hybridomas. The instruments are currently housed in the Chemical Engineering Department.

Flow Labs: Flow Labs donated a Cell Raiser bioreactor (\$23,000) to Dr. Herr's lab.

Humagen Fertility Diagnostics: this company, founded by Dr. Herr in 1985, is located in Charlottesville, VA, and manufactures the Penetrak assay, a measure of sperm penetration in cervical mucus for Serono Diagnostics. In addition, the company manufactures pipets for IVF and licenses UVA patents held by the University of Virginia Patents Foundation on forensic assays for rape and blood detection. Dr. Herr worked closely with then Governor Charles Robb's Office of Economic Development to consolidate the venture capital for this enterprise and served as the Chairman of the Humagen Scientific Advisory Board from 1987-1989. In 1996 the company expanded its manufacturing facilities in Charlottesville, Virginia and currently employs ~45 persons.

Ortho Pharmaceuticals From 1991-1992 Ortho conducted Contract research within the Center for Recombinant Gamete Contraceptive Vaccinogens. This resulted in direct funding to the Herr lab, costs for animal and primate trials as well as funds for human trials, and royalties to the University.

ContraVac In 1992 Dr. Herr founded ContraVac as a corporate shell to receive technology emanating from the Center for Recombinant Gamete Contraceptive Vaccinogens. ContraVac has licensed several of Dr. Herr's patents and is currently developing a male infertility diagnostic, Sperm Check™ in co-operation with a strategic manufacturing partner, Princeton Bio Medi Tech Corporation. Dr. Herr is working to attract this company to the University North Fork Industrial Park.

Schering, AG In 1998 this company finalized contracts with the University of Virginia and the University of Virginia Patents Foundation to license technology developed in Dr. Herr's and Dr.

Flickinger's laboratories. The contracts have resulted in funding for development of young faculty as well as future patent royalties and provides a strategic partnership for translational research.

#### Graduate Student Thesis Committees Served

Pat E. Bender (L. Rebhun, Major Advisor) Biology (Graduated, 1981)  
Fritz Reinhart (R. Bloodgood, Major Advisor) Anatomy  
Lynn Samuels (C. Flickinger, Major Advisor) Anatomy (Graduated, 1984)  
Wendy Wilson (G. Oliphant, Major Advisor) Anatomy (Graduated, 1986)  
David Wolpart (D. Kirwan, Major Advisor) Chem. Engineering  
Greg Dandulakis (co-advise with D. Kirwan) Chem. Engineering (Graduated, 1997)  
Tina Garza (K. Tung) Pathology (Graduated, 1998)  
Bernard Dukes Microbiology (Graduated, 2000)  
Tom Gervais (Chemical Engineering/Biotechnology) (Defended July, 2002)  
Heping Gheng (Physiology and Molecular Biophysics)  
Yan Ge (Rheumatology- Shu Man Fu)

#### Graduate Student Rotations in Lab

Samuel Waters - CMB - 1994  
Elizabeth Norton - Biotechnology - 1994  
Connie Grafer - Biotechnology - 1994  
Amy Butscher - Biotechnology - 1995  
Todd Armstrong - Cell Biology - 1995  
Rob Baskin - Molecular Medicine - 1996  
Theresa Robinson Thompkins – 2000  
Jamie Rolle -2004  
Isabel Gonzales-2004

#### Undergraduate Biology Students Supervised for 495 Projects

1982	Sun Woo Lee
1982	Dana Buchanan
1982	Thomas Gallien
1984	Tracie Rankin
1984	Mike Slattery
1988	Kim Snyder1994-95 Liz Dedman
2001	Maria Chamura
2002	Alexandra Garcia
2003-05	Margaret Samra (won second place in the undergraduate senior thesis competition for her work in the laboratory)

#### Hughes Scholar Undergraduate Research Program

Brian Kornreich 1990-1992 A Howard Hughes scholar from Biology, Brian worked on the expression of the SP-10 sperm vaccine immunogen. His work won the 1991 Sigma XI Undergraduate Research Award at UVA for his work in the lab.

### Medical Student Summer Training (MSTP)

Beverly Boykin	1984	worked on hybridoma production
Tim McGarry	1984	poster on work presented, October 23, 1984, MSTP Poster Session
Andrew Sager	1985	poster on work presented, October 22, 1985, MSTP Poster Session
Tim Polk	1987	Tim worked on immunocytochemistry of the human prostate
Carl Palmer	1989	work on gene cloning from human testis
Ray Dumaran	1989	gene cloning human testis
Samuel M. Brooke	1991	Inhibition of hemi-zona assay by baboon sera to recombinant vaccine.
Renuka Bhattacharya	1994	Monkey oviductal immune response

### Medical Minority Academic Advancement Program

1990	Five minority summer students received laboratory experience.
1991	Tounia Louder, a high honor student received training during the summer of 1991.
1996	Joe Boyd (Native American); Jacqueline Barrientos (Hispanic) - spent their summers in the Herr lab.
1997	Glen Davis II (African American) spent the summer in the Herr Lab. Four minority summer students all African Americans, received laboratory experience in the Herr Lab: Fred Cesar, Nieka Harris, Erica Kinney, and Tericka Smith.
1999	Two minority summer students both African Americans, received laboratory experience in the Herr Lab: Gregory Dairyko and Erica Kasper.
2000	Five minority summer students: four African Americans, one Caucasian American, received laboratory experience in the Herr Lab: Janice Hobbs, LaRhonda Jackson, Kwame Osei-Sarfo, Rachel Simpson, and Melissa Stokes.
2001	Six minority summer students: four African Americans, one Caucasian American and one Native American, received laboratory experience in the Herr Lab: Tanishesha Buffin, Ugochi Ekeocha, Eline Haenebalcke, Denise Mayo, Natalie Melrose and Bernadette Ramone.
2002	Five minority summer students: three African Americans, one Caucasian American and one Native American, received laboratory experience in the Herr Lab: Craig Foster, Pierre Gordon, Michelle Morse, Sanet Torres and Nia Washington Plaskett.
2003	Four minority summer students, all four African American, received laboratory experience in the Herr Lab: Kara Malone, Jaime Rolle, Melecia Simpson, Kimberly Wiggins

### Activities to Develop Pre-and Postdoctoral Training Resources

Dr. Herr has organized, written, and serves (or served) as program director for several pre- and postdoctoral training programs.

**Graduate Training:** The Biotechnology Training Grant, a multidisciplinary training program between five basic science departments in the Medical School, Chemistry and the Dept. of Chemical Engineering, was organized and funded by NIH in 1990. Four positions in the first year expanding to six predoctoral positions in the second year were awarded.

**Postdoctoral Training:** A postdoctoral training program was funded in 1990 within the Center for Recombinant Gamete Contraceptive Vaccinogens which included six postdoctoral positions [five years of funding]. The program will be refunded until 2002.

**International Postdoctoral Training:** A NIH Fogarty Fellowship Program which funds 4 fellows from India was funded for 5 years beginning in 1995. In 1997 NIH asked if the program would like 2 additional slots and awarded these positions as part of a new initiative in male contraception. In October 2000, the program was competitively renewed for five years with 6 approved positions.

**Minority Training:** A summer research internship program in reproductive biology for 6 minority undergraduates was funded for 3 years beginning in 1996 by the Mellon Foundation. The program was refunded in 1999 for an additional 3 years.

### Activities to Develop New Construction Funds

In 1999 Dr. Herr worked on Capital Hill to improve funding for new construction in the National Center for Research Resources at the NIH. On March 1, 2000 he developed a \$2 M grant to NCRR to aid in the construction of the Medical Research-6 Building at the University of Virginia.

11/09/2005



Name:

Jagadeesh Srinivasan

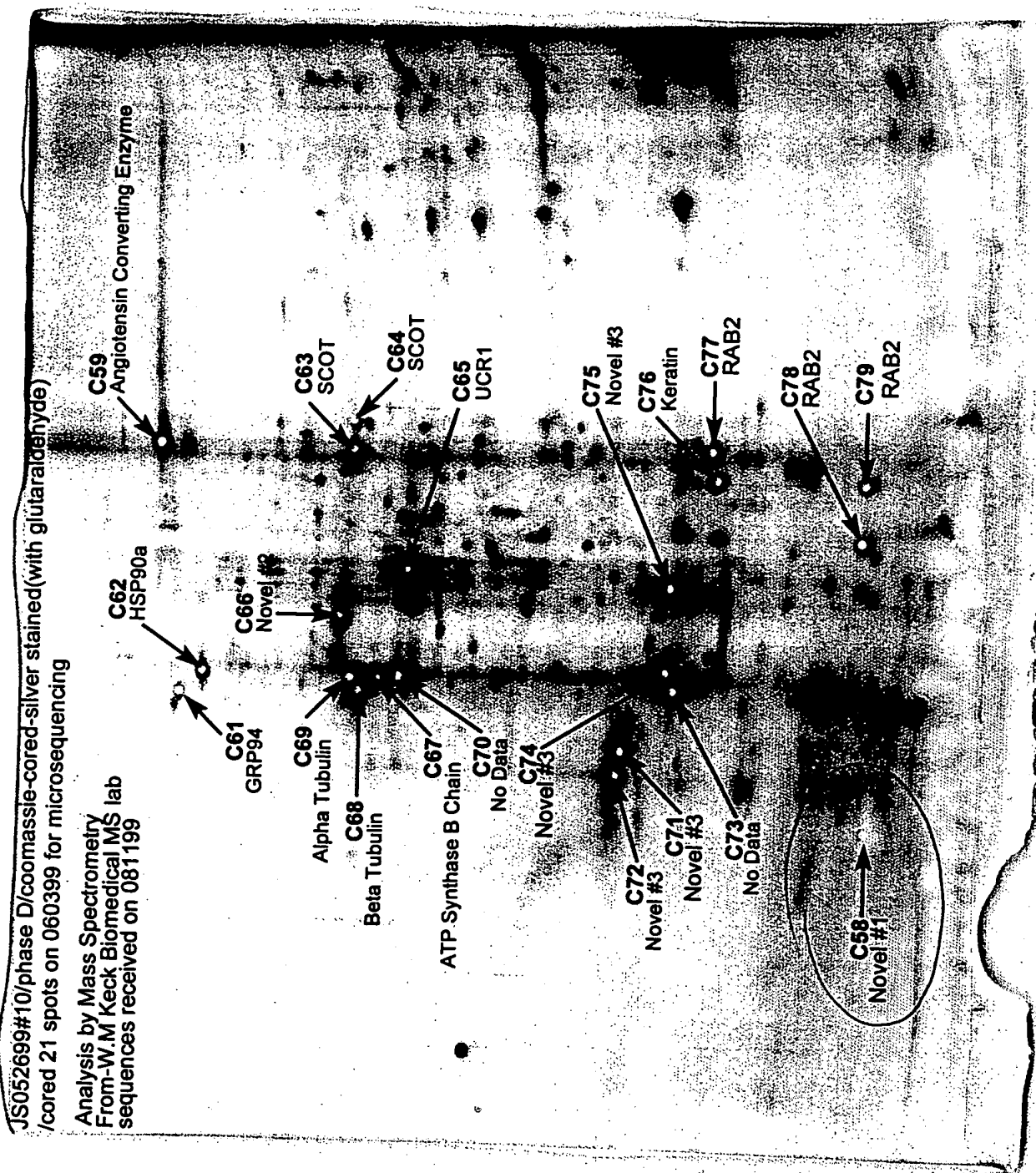
Date:

8/12/99

Experiment:

039

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10/809, 654

EXHIBIT 1

Name: Jagathpala Sheth

Date: 8/15/99

Experiment:

Report number: 400

Sequence Analysis of 22 2D Gel Bands.

8/11/99

**Band C58.** The peptides shown in Table 1 were detected in Band C58 (LB6-43-1). These peptides belong to Novel #1.

Table 1. Peptide sequences from Band C58 (LB6-43-1).

Peptide No.	Measured MW (M+H <sup>+</sup> , Da)	Peptide sequence by CAD <sup>1</sup>
1	1482.8 +2	ATSC <sup>a</sup> GLEEPVSYR
2	1499.4 +2	ATSC <sup>a</sup> (o)GLEEPVSYR
3	5033.8 +5	--- XSDSMEC <sup>a</sup> ---
4	5049.7 +5	--- XSDSM(o)EC <sup>a</sup> ---

GLEEPVSYR ~ 9mer

<sup>1</sup>I and L cannot be distinguished by low energy CAD but are inferred by the database sequence, M(o) designates oxidized M, C is carbamidomethyl modified unless noted as C<sup>a</sup> (acrylamide), \_ designates a single unknown residue, --- designates an unknown number of unknown residues.

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Name: Jagathpala Sheth

Date: 8/15/99

Experiment:

042

Nucleotide and deduced amino acid sequence of Human Testis EST (Accession # AA778671) which matched to tryptic peptide obtained by Mass spectrometry of c

Soares Testis NHT Homo sapiens cDNA clone 1049023 mRNA sequence. ACCESSION AA778671

1 GCCTGGTCCGGTCATCAACAAAGGCTGCCTGCGAGCCACCAGCTGCGGCCTTGAGGAAC 60  
T G P V I N K G C L R A T S C G L E E P  
61 CCGTCAGCTACAGGGGCGTCACCTACAGCCTACCACTGCTGCACCGGCCGCTGT 120  
V S Y R G V T Y S L T T N C C T G R L C  
121 GTAACAGAGCCCCGAGCAGCCAGACAGTGGGGGCCACCAGCCTGGCACTGGGGCTGG 180  
N R A P S S Q T V G A T T S L A L G L G  
181 GTATGCTGCTTCCCTCCACGTTTGTGTGACCAACAGGGAGGACAGGGCCTGGGACTGTTC 240  
M L L P P R L L \* P T G R T G P G T V L  
241 TCCAGATCCGCCACTCCCCATGTCCCCATGTCCTTCCCCACTAAATGGCCAGAGAGGC 300  
P D P P L P M S P C P S P T K W P E R P  
301 CCTGGACAACCTCTTGCGGGCCCTGGCTTCATCCCTTCTAAGGCTGTCCACCAGGAGCCCC 360  
W T T S C G P G F I P S K A V H Q E P G  
361 GTGCTAGGGGAAGCATCCCCAGGCCTGACTGAGCGGCAGGGGAGCACGGCCCGTGGGTTT 420  
A R G S I P R P D \* A A G E H G P W V \*  
421 GATTGTATTACTCTGTTCCTGTTCTAAGACGCAGAGCTTCTCATCTCAATCAGGA 480  
L Y Y S V P L V L R R R A S H I S I R M  
481 TGCTTCTCTCCATTGGTAGCACTTTAGAGTCCATGAAATATGGTAAAAAATATATATATA 540  
L L S I G S T L E S M K Y G K K Y I Y I  
541 TCATAATAAATGACAGCTGATGTTCAAAA 569  
I I N D S \* C S K

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Name: Jagathpala Sheth Date: 05/26/99  
 Experiment: PCR to generate C58-partial cDNA

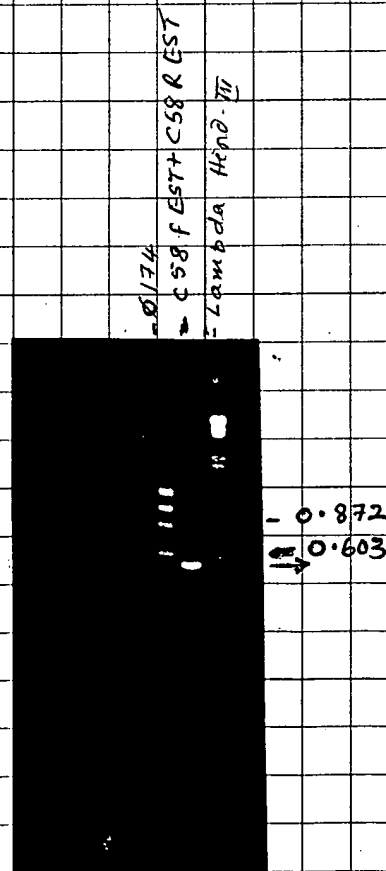
043

PCR both primers for C58-EST  
 using both forward and reverse primers.

Bottom:		Top:
3.025	3.8 bf	4.55-
2	4 dNTP	
2	100 $\mu$ g	
1.25	GSPF (C58-F-EST)	
1.25	GSPR (C58-R-EST)	
0.475	H <sub>2</sub> O	7.95
	cDNA	2
	polyase	0.5

### PCR programme

- ① 94 2:30
- ② 94 1:30
- ③ 68 1:30  
 $\Delta - 15/\text{cycle}$
- ④ 68 2:30
- ⑤ Goto 2 (11x)
- ⑥ 94° 1:30
- ⑦ 50° 1:30
- ⑧ 68 2:00
- ⑨ Goto 6 (27x)
- ⑩ 68 18:00
- ⑪ 60° 10



Result: Obtained a product around 530 bp. which matched to the expected product i.e. 519 bp.

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Name: Jagathpali Sheth Date: 9/7/99  
Experiment:

048

The sequence for c58 est was  
obtained from the sequencing lab.

Sequence of PCR-derived EST  
9/7/99  
partial sequence for c58

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!!NA\_SEQUENCE 1.0

Sequence of PCR-derived EST from 9/7/99

c58est.dna Length: 475 September 7, 1999 12:00 Type: N Check: 5379 ..

```
1 CTGCGGCCTT GAGGAACCCG TCAGCTACAG GGGCGTCACC TACAGCCTCA
51 CCACCAACTG CTGCACCGGC CGCCTGTGTA ACAGAGCCCC GAGCAGCCAG
101 ACAGTGGGGG CCACCACCAG CCTGGCACTG GGGCTGGGTA TGCTGCTTCC
151 TCCACGTTTG CTGTGACCAA CAGGGAGGAC AGGGCCTGGG ACTGTTCTCC
201 CAGATCCGCC ACTCCCCATG TCCCCATGTC CTTCCCCCAC TAAATGGCCA
251 GAGAGGCCCT GGACAACCTC TTGCGGCCCT GGCTTCATCC CTTCTAAGGC
301 TGTCACCAG GAGCCCGGTG CTAGGGGAAG CATCCCCAGG CCTGACTGAG
351 CGCAGGGGA GCACGGCCCG TGGGTTTGAT TGTATTACTC TGTCCACTG
401 GTTCTAAGAC GCAGAGCTTC TCACATCTCA ATCAGGATGC TTCTCTCCAT
451 TGGTAGCACT TTAGAGTCCA TGA
```

Important: Place card under blue copy.

EXHIBIT 5

Name: Jagathpala Sheth Date: 9/7/99. <sup>testic cDNA</sup>  
Experiment: cloning of CS8 (Screening of Library) 050

A culture of K 802 strain host ~~is~~ was made.

medium used : NZCYM medium.

20ml of NZCYM + 20% of 20% maltose soln  
(Actual conc is 0.2% in the medium)

K 802 cells host strain taken from  $-70^{\circ}\text{C}$   
with a sterile tip taken out and  
placed inside the medium.  
Kept at  $37^{\circ}\text{C}$  - Shaker.

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Laboratory Research

Important: Place card under blue copy.

EXHIBIT 6

Name:

Jagathpala Shethi

Date:

09/08/99.

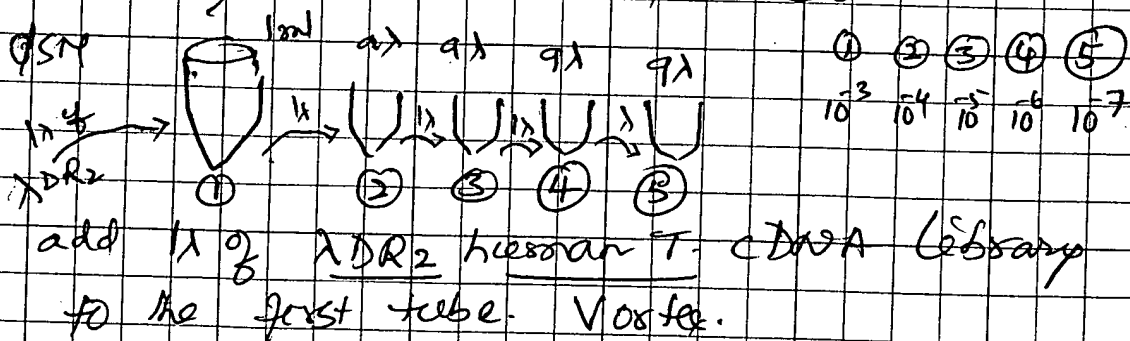
Experiment:

Cloning of c58

051

Titration of the  $\lambda$  DR2 Library.(  $\lambda$  DR2 - human Testis cDNA Library )

- ① The NZCYN medium was thawed using microwave.
- ② About 20  $\mu$ l each of the medium was ~~plated~~ poured on 5 plates and the cap was kept open (in the sterile hood)
- ③ Clean time Take the culture of K802 left at 37°C previous day. and Take
- ④ Take 1ml of  $\phi$ SM buffer (buffer for  $\lambda$  DR2 i.e. phage buffer) in a tube. and 9  $\mu$ l each to 4 tubes.



Take 1  $\mu$ l from tube 1 to tube 2, vortex and take 1  $\mu$ l from #2 & transfer to 3 and so on. vortex.

Take 1  $\mu$ l each from each tube and to a 10  $\mu$ l tube. (spread bottom).

Important: Place card under blue cover

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National Brand

Laboratory Research

EXHIBIT 7

Name: Jagathpala Sheth

Date: 09/08/99

Experiment:

052

- ⑤ Add 75 $\mu$ l each of the K802 culture to all tubes. - wait for 20 minutes.
- ⑥ Melt the thaw NZCYM- agarose (or 7?) medium and allow it to come to  $\approx 50^{\circ}\text{C}$  (for the top layer)
- ⑦ Keep a water bath at  $37^{\circ}\text{C}$  with a thermometer.
- ⑧ Keep the tubes at  $37^{\circ}\text{C}$  for 2 minutes
- ⑨ Take  $\approx 1/4$  ml of the melted ~~agar~~ NZCYM agarose - in to the tubes <sup>containing the</sup> ~~pour~~ <sup>contents from the tubes to the LB</sup> ~~the~~ <sup>Agar plates, swirl the plates as you</sup> ~~pour~~ <sup>pour</sup>. Allow it to cool. for 10 min. to allow the inoculum to soak into agar.
- ⑩ Incubate plates at  $37^{\circ}\text{C}$  O/N.

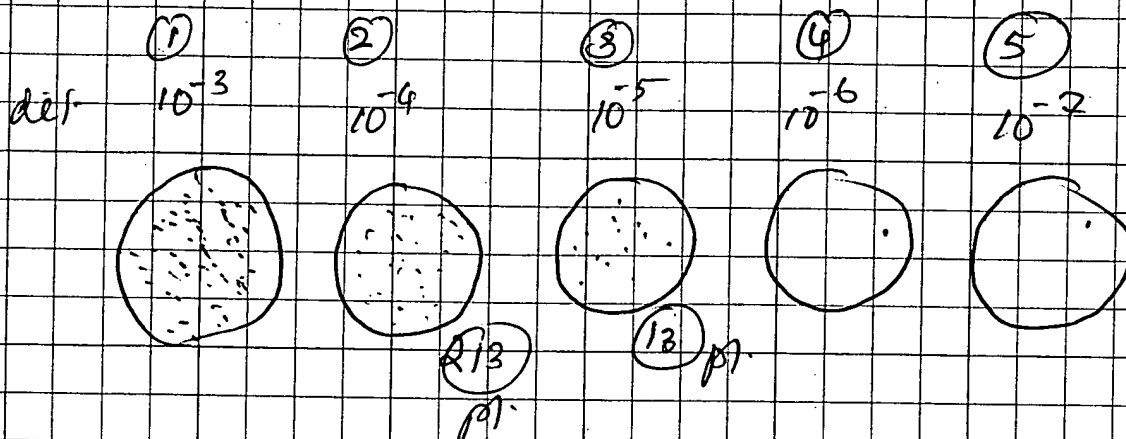
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Name: Sergathpale Sush Date: 09/09/99.  
 Experiment: Screening of Library

053

The plaques on the plates counted.



#(1) i.e. too many

#(2)  $213 \times 10^4$  i.e.  $2.13 \times 10^6 / \lambda$

#(3)  $13 \times 10^5$  i.e.  $1.3 \times 10^6 / \lambda$

average  $\approx 1.7 \times 10^6 / \lambda$

average phage to be used for screening  $\approx 40 \times 10^4$

note  
 $\lambda$  dilute  $\rightarrow 100 \lambda$

i.e.  $\lambda \rightarrow 17 \times 10^3$

can take  $\approx 2.5 \lambda$  i.e. g

gives  $\approx 50 \times 10^3$  phage

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Name: Jagathpala Sheth

Date: 09/09/99

Experiment:

054

### Transfection of host strains

Poured 6 bigger plates with D2CYP  
poured 50 ml each (1.3% agar <sup>medium</sup>)

Taken a small crystal of library ~~cell~~  
XDR from  $-70^{\circ}\text{C}$  and the stock kept  
back.

Take 1x  $\rightarrow$  det. 100x

205x  $\rightarrow$  should give  $\approx$  50,000 phages

The bugs in 10 ml of D2CYP with 2% sorbitose  
— spun  $\rightarrow$  pellet taken and  
resuspended in 405 ml of 10 mM  
Tris pH 8.0

Taken 600x each from 6 tubes  
of bugs + 15x of phage.

620x of cells  
15x of phage (1:100 diluted)

$\downarrow$  20 minutes

$\downarrow$   
Take 100x each and  
add to 6 tubes.

Heat time top agarose at  $50-55^{\circ}\text{C}$

Important: -

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10/809,654

EXHIBIT 10

Laboratory Research

National "B" and

Name: Jagathpala Shetty Date: 09/09/99  
Experiment: Screening of Library

056

## DNA Labelling

Protocol: Reinberg & Voelstein Method

TO a sterile microfuge add:

C-58-EST	DNA <del>5</del>	(= 50 ng)	in 2 $\mu$ l
	H <sub>2</sub> O		3 $\mu$ l
		incubate 5 min	
oligo labelling bf.	OLBf		10 $\mu$ l
	[ $\alpha$ - <sup>32</sup> P] dCTP		5 $\mu$ l
	Klenow		1.5 $\mu$ l

\* After adding OLBf keep at -20 for a while.

Add 5  $\mu$ l of  $\alpha$ -<sup>32</sup>P dCTP and  
1.5  $\mu$ l of Klenow. Incubate for a  
while and leave at 37°C.

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Name:

Jeyathirupala Shethi

Date:

09/10/99.

Experiment:

cloning of CSB Contd. (Library screening) 057

The plates - taken out from  $37^{\circ}\text{C}$  and chilled at  $4^{\circ}\text{C}$ .

### Membrane lifting

① The nylon membranes - 6 of them numbered and 3 marks. Were done at 3 corners - randomly.

② Membrane - placed on the plate carefully in one attempt. (Do not lift and change the position). - Leave for 2 min. (using tweezers)

③ Lift - make 5 marks with syringe needle. also make 1 mark on the side of the plate corresponding to penicillin on filter. Take the membrane carefully and place it on a Whatman paper soaked

with chloroform in Soln - 5-10 min. Filter should be placed phase side up.

Change positions in order ensure the complete immersion of the filter in the solution.

④ Place the membrane on a Whatman paper containing Neutralization buffer. Change positions - ensure completely immersed and - 5-10 minutes

⑤ Cross-linking:



- ① place inside on a Whatman
- ② press power on

Important:

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EXHIBIT 12

Laboratory Research

National Brand

Name: Jagathpala Sheth Date: 09/10/99  
Experiment: screening of testis library

058

- (2) hit auto cross link
- (3) start - 9x will start at 1200 come down to zero.
- (4) Dry the blots.
- (5) The plates are wrapped in saran wrap and placed at  $4^{\circ}\text{C}$ .
- (6) The filters are ~~kept~~ placed in a tray ~~where~~ in d. H<sub>2</sub>O containing ~~2x~~ 2x SSC & 10.2% SDS to remove any protein & debris at  $42^{\circ}\text{C}$ . (15-30 min.)  
(This step not crucial)
- (7)

### Prehybridization

Soln: Total 2 L total

20 ml	Spermidine
8 ml	SSC 25x
4 ml	Deinhardt's - (stored at $4^{\circ}\text{C}$ )
2 ml	NaPO <sub>4</sub>
4.2 ml	H <sub>2</sub> O
2 ml	yeast RNA
0.8 ml	<del>25x</del> 25% SDS - (add last)

Filter the solution using a 50 ml syringe to a 50 ml tube.

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Name: Jagathisala Srath Date: 09/10/99

Experiment: C58 - cloning - contd (screening of Library)

059

- \* Open a food bag at one end.
- \* Take the letter out using a folded what man and put it to the bottom of the bag.
- \* Seal ~~the~~ one side of the bag. - 2 seals.
- \* Pour about 20 ml of the <sup>formaldehyde</sup> presyb. solution
- \* <sup>same 20 ml for hybridization</sup> Push the air bubbles out carefully.
- \* Seal the top - 2 seals.
- \* ~~Pour about 20 ml of the presyb. soln.~~
- \* Keep at 42°C - 3 hrs.

~~Purification of~~

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## Purification of the probe (DNA)

DNA purifying column - ~~end at the top~~

Remove the bottom cover. Cut the top off just below the matrix. Remove the plug off. ~~is~~ Take out the plunger. insert into a

5 ml Syringe.

\* ~~Load~~ equilibration of the column :- 5 ml of Elutip.

(low salt soln) - ~~slowly~~ Put the plunger and slowly - steadily elute out the equilibration of. to a 15 ml tube.

\* Take the labelled DNA (crude). Take  $\approx$  900 ml of Elutip (low salt) :- ~~Elute out the equilibration~~ buffer. Add one more ml of Elutip.

\* Put the plunger and slowly push the plunger and get the unlabelled DNA to a 15 ml tube.

Add  $\approx$  4 ml of the Elutip to the syringe. (Each time you reload the buffer disconnect the syringe, take the plunger out & then load sample)

\* Disconnect the column. Connect to a 2 ml. fresh syringe (take the plunger out before connecting). Load  $\approx$  1/2 ml of high salt solution.

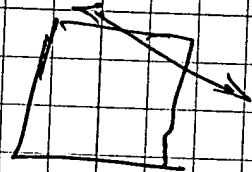
Name: Jyothipala Sneh Date: 09/10/99  
Experiment: C58. Cloning - contd.

061

Replace the plunger and collect the labeled DNA to a low microfuge tube.

### Hybridization.

- \* Take out the membrane in the bag  
Make a cut across the corner.
- \* Pour off the soln to sink.
- \* Take the purified probe and boil it for 5 min. (Open the tube in between (after ~40 sec) and release press.)
- \* Take 20  $\mu$ l of the hybridization buffer (saved from earlier prehybridization step) and add the labeled DNA to it.
- \* Pour this into the bag containing membrane.
- \* Carefully remove the air bubbles out.
- \* Seal safely - 2
- \* Get the remaining bubbles to the corner and seal again.
- \* Clean all the areas.



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EXHIBIT 16



Name:

Jagathpala Sheth

Date:

09/11/99

Experiment:

C58- cloning- contd.

062

Washing of the membranes

- \* Take out the bag, out the corner down <sup>to add</sup> <sub>cooler</sub>
- \* Take out the membranes after cutting rough
- \* 3 sides
- \* Place the membrane inside pour 200ml of the washing soln 1.

① Washing soln 1:

2X SSC made from 25X SSC in  
SDS - 0.2% (200ml H<sub>2</sub>O)

- Pour a small volume pour off after giving ~~small~~ a short wash. Pour 200ml of solution ~~and~~ (solution at RT) and put the tray at 42°C - 20 min.  
(It will come slowly to 42°C by 20 minutes).

② Washing Step 2:

0.2% SSC & 0.2% SDS - (200ml at 42°C)

prewarm the solution to 42°C.  
incubate membranes - 20 min

③ Washing Step 3

200ml of 0.2X SSC & 0.02% SDS - 20 min  
prewarm to 50°C (preferably 52°C)  
incubate membranes - 20 min.

Important: Place card under blue cover

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EXHIBIT 17



Laboratory Research

Name: Jagathpala Sheth Date: 09/13/99.  
Experiment: C58 cloning - Contd.

063

## Exposing the membranes

Take membranes in little 0.2 SSC and 0.2% SDS.

Take Cassette - mark ..

Place the Int. Screen on a flat surface on the bench place a s-wrap long enough. Place all the membranes in order.

fold the s-wrap. Place upside down. Fold the sides properly.

Place this on the cassette

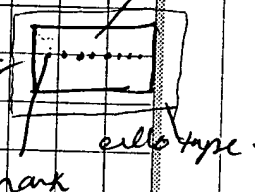
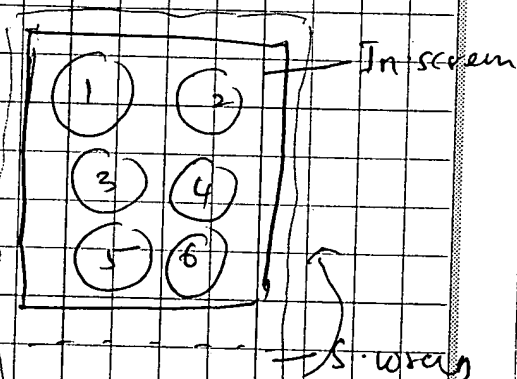
the marked side up. (Phase & side is down).

Take small piece of paper containing ind-p32. cut pieces containing one or two dots and paste sandonip.

Place one Int. Screen on

the top.

Take to the dark room place ~~an~~ a X-ray film & then another Int. Screen - put at -70°C



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EXHIBIT 18

Name:

Jagathpala Sheth

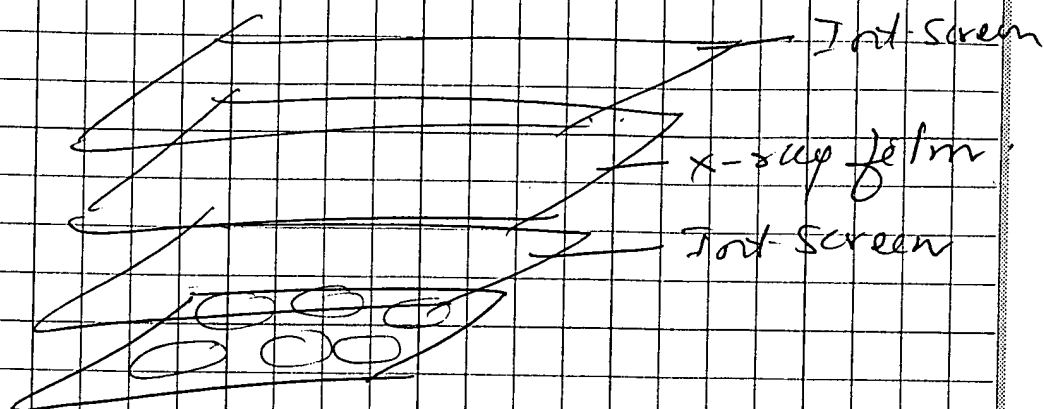
Date:

9/1/99

Experiment:

064

9/1/99



9/13/99

Exposed film taken out - One more film put in.

Align the film to the membrane and get to all the marks. Make an imprint on the x-ray film.

(preferably use diff. colours for different markings i.e. for periphery of the plates, side marks and 5 dot marks inside the membranes.

Mark the spots to be picked on the x-ray.

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Name:

Sargathpala Shetty

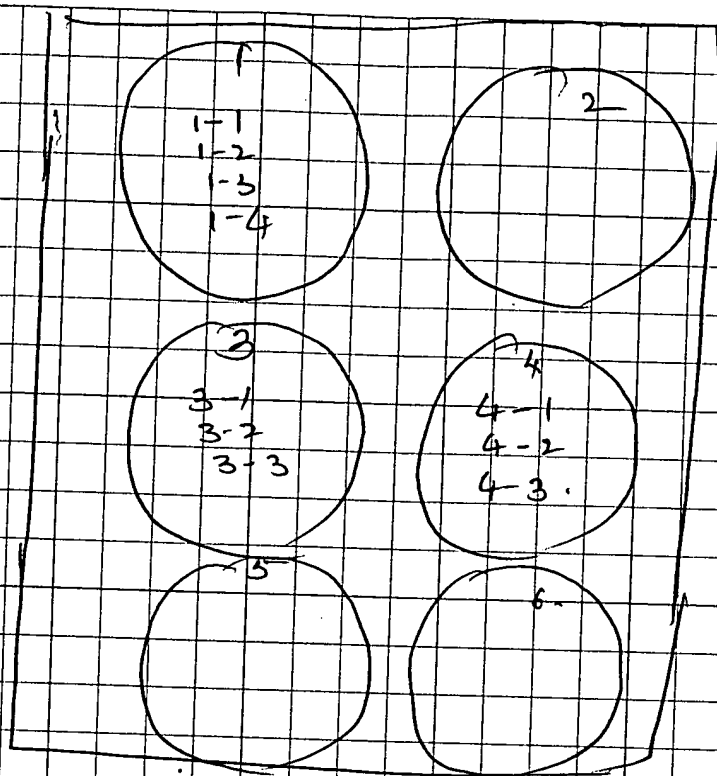
Date:

09/13/99

Experiment:

C58 cloning - contd

065



Decide about  
the spots to be  
picked.

~~Plus~~ Pipette 0.4 ml of DSN to 10 ml  
tubes.

Aspirate the agar from the plate - shown  
positive into tubes containing 0.4 ml  
of DSN.

put  $\approx$  5  $\mu$ l of Chloroform to each  
tube. (increases in yield & also  
sterilizes).

↓  
put on a vortexing platform at  
4°C for about 1-2 hrs

↓  
Keep at 4°C till use.

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Laboratory Research

National Brand

10/809,654

Important:

EXHIBIT 20

Name: Jyothipala Sheth

Date: 09-14-99

Experiment: C58 cloning- contd.

066

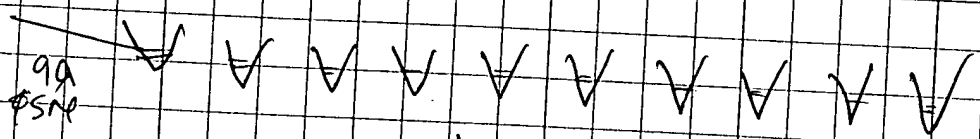
## Secondary Screening

Positive phages - taken out from 4°C

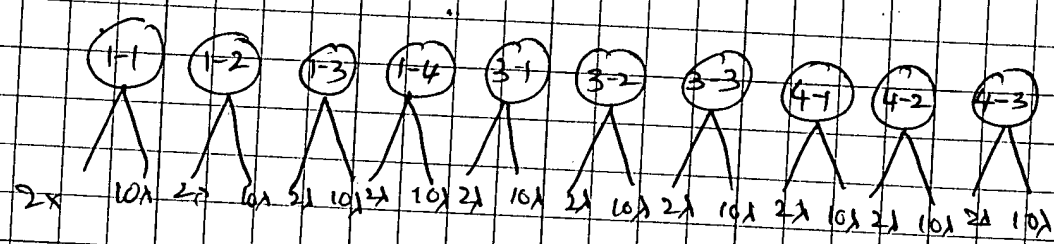
Spin ↓ 2 minutes

PSM → 90% to 10 tubes

1% of  
+ phase sup.



↓  
Vortex.



Mean time. 20 plates poured - NZCM agar.  
After solidifying, bottom - marked  
with the ~~members~~ corresponding members.

NZCM - agarose - melted - kept at 50°C.

Taken 2 tubes at a time containing  
phage - kept at 50°C for 2 minutes.

↓  
Add 4 ml of NZCM - agarose

↓  
poured a top layer on the plates  
& allowed to solidify

↓  
left at 37°C.

Important.

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EXHIBIT 21

## DNA labelling:

50 ng of C58 - labelled as before.

A/15/99

## Secondary lifting

Plates taken out from 37°C.  
In each pair the plate showing  $\approx 200$  phage selected

10 nylon (8mm dia) - soaked

A left was soaked as before

Denaturation (5-10 min)

NaOH (0.5M)  
NaCl (1.0M)

Neutralization (5-10 min)

0.5M Tris  
1.5M NaCl

Cross link

Drop the plates membranes

wash at 42°C with 2xSSC + 0.2% SDS (30 min)

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Name:

Jagathpala Shah

Date:

09/05/99

Experiment:

C58 Cloning - contd.

068

C58  
Sec.

## Prehybridization & Hybridization Membranes

↓  
put in food bag (seal sides)

↓  
pour prehyb solution

↓  
3 hrs.

↓  
purify the labelled DNA  
using elutip. in 500s

↓  
500  $\mu$ g labelled DNA + 415 ml of  
hyb solution

↓  
The bag opened & prehyb  
soln. poured to sink

↓  
The hybridization done O/N  
with the label + hyb soln.

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EXHIBIT 23

Important:

Name:

Jagathpala Sheth

Date:

09/16/99

Experiment:

ESB - Cloning - Contd.

069

## Washing of Membranes

① Discarded the lyp. solution



I Wash 2x SSC, 0.2% SDS - 20 min.  
 $\approx 200 \text{ ml}$  30  $\rightarrow$  42°C.

II Wash 0.2x SSC, 0.2% SDS - 20 min. 42°C  
 $\approx 200 \text{ ml}$

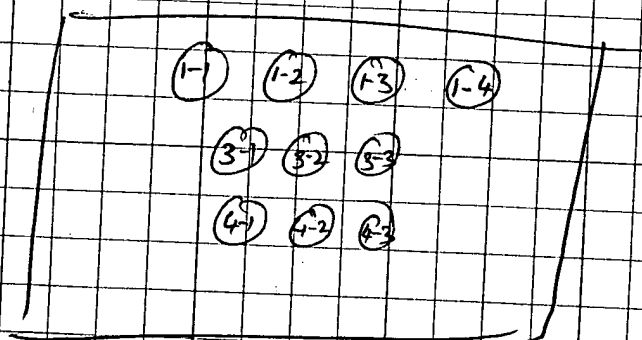
III Wash 0.2x SSC, 0.2% SDS - 20 min. 42°C.  
 $\approx 150 \text{ ml}$



Membrane taken in 50 ml of 0.2x SSC & 0.2% SDS.



aligned on the saran wrap.



exposed at 11-45 AM.

09/17/99

Film developed and ~~to~~ marked respective to plates.

EXHIBIT 24

Important:

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Name: J. Shetty

Experiment:

Date: 09-20-99

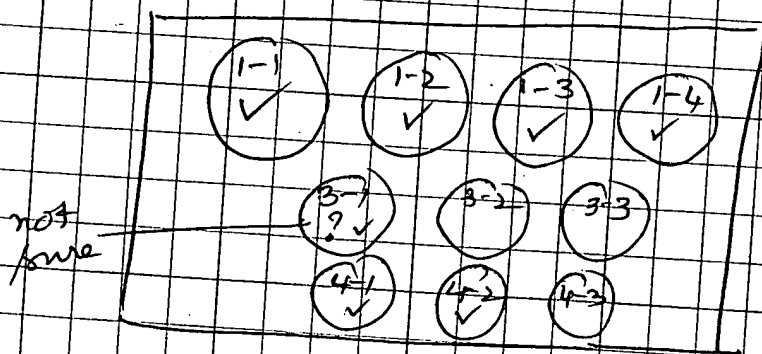
070

APC cells inoculated in 10ml LB + 1g tetracycline  
3 hrs. at 32°C shaker.

Spin the cells

Take pellet in 10mM MgSO<sub>4</sub> (1ml)

Align the gel on the membrane and then  
to the plate - mark the active clone (isolated)  
from the back of the plate.



picked one  
clone each  
from the  
marked ones.

into 1ml tube  
with 0.5ml of DMSO

5x of cells  
↓ 4°C shaker  
↓ 1-2 hrs

Give a quick spin  
to settle again

30 minutes } Take 15x from the sup  
at RT } 32x of APC cells

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EXHIBIT 25

National Standard  
Laboratory Research

Name: Jagadipala Shethi

Experiment: C58- cloning- contd.

Date: 09-20-99

071

continued from previous page

Add 50  $\lambda$  of broth (LB) (recombination & circularization)  
1 hr. Shaker water bath at 32°C

Add 2 ml of 10 mM IPTG  
to induce replication of recombinant pDR<sub>2</sub>

1 hr. Shaker water bath at 32°C

Add 1  $\lambda$  of ~~500~~ 500  $\mu$ g/ml Carbenicillin  
& 1  $\lambda$  of 1 M Sod. citrate  
(for preferential existence of pDR<sub>2</sub> over pDR<sub>1</sub>)  
32°C for 1 hr.

5  $\lambda$  Spread on LB-Agar plates.  
as follows.

20  $\lambda$  of  
Carbenicillin  
500  $\mu$ g/ml

40  $\lambda$  of Sod. citrate  
(1 M)

5  $\lambda$  or  
50  $\lambda$  of  
phosphate  
mix



Spread  
with sterile  
spreader

o/n: 37°C

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10/809,654

EXHIBIT 26

Oratory Research

National Brand

11/12

11/12

Name:

Jagathpala Shethi

Experiment:

C58-cloning. contd.

Date:

9/21/99

072

The plates observed and allowed to  
grow to larger size at  $37^{\circ}\text{C}$ .

Left at RT for some time.

Inoculation of ~~to~~ to 3ml LB cultures

Stock of 50ml LB + 75% of Amp<sup>r</sup> (50mg/ml) <sup>from stock</sup>  
made & divided 3 ml each tube (10ml tubes)

Pick a single isolated colony using toothpick  
choosing any one from a pair

inoculate to LB Amp.

Shake in water bath -  $37^{\circ}\text{C}$  O/N.  
(for 3-1- 2 colonies picked  
ie: 3-1a & 3-1b)

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EXHIBIT 27

atory Research

National Brand

Name: Jagadpala Sheth Date: 09/22/99  
Experiment: Cloning of C58

073

O/N culture of A293 cells

↓  
Qiagen kit isolation of DNA from plasmid

1. Cells pelleted out 2 steps.

Get - Take 1.5 ml into 1.5 tube - Spin (1 1/2 min)  
discard supernatant, add another  
1.5 ml and take the supernatant  
using vacuum-dispenser.

Follow the Qiagen kit protocol to isolate DNA

① ~~dislodge pellet~~ Add 0.3 ml of Bf P1  
dislodge pellet using P-200 pipettor

② Add 0.3 ml of Bf P2 - invert 4-6 ~~times~~  
times - sit 5 minutes

③ Add 0.3 ml of P3 - ~~slowly~~ <sup>soak at 4°C</sup> invert 4-6  
times - keep on ice - 5 minutes  
↓ Spin - 10 minutes

④ Clean while set up the Qiagen column.

equilibrate the column with  
1 ml of QBT

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EXHIBIT 28



Laboratory Research

Name:

Jagathpala Sneh

Date:

09-22-99

Experiment:

Cloning of C58

074

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EXHIBIT 29

Laboratory Research



- ⑤ Take the Supernatant carefully from step ③ leaving the upper layer and the lower viscous pellet and load to the column carefully.
- ⑥ Wash the column with 10ml x 4 (times) of solution QC. wait till last drop. Put the tube at the bottom of column.
- ⑦ Elute DNA with 0.8 ml of QF. wait till last drop.
- ⑧ Discard the column.
- ⑧ Add 0.56 ml of isopropanol.
- ⑨ Spin for 30 minutes, 12,000 rpm.
- ⑩ Take sup. with fine tipped pasteur pipette with a bulb.  
(Make one fine tipped pasteur pipette)
- ⑪ ~~Give~~ a carefully load 200  $\mu$ l of chilled 70% ethanol and once again take the sup. off.  
(\* DO not disturb the pellet)  
↓  
Air dry.

Important:

Name:

Jegathpala Sneh

Date:

9-22-99

Experiment:

Cloning of c58

075

Dissolve DNA in 20 $\mu$ l of sterile water  
 keep on shaker at 4 $^{\circ}$ C - 15 min

↓  
 Shake again at  $\approx$  20 $^{\circ}$ C with  
 vortex mixer - 3-5 minutes

↓  
 Give a quick spin.

Digestion of plasmid with BamHI  
 and XbaI

BamHI

XbaI

insert

(usually buffer conditions  
 are different for 2 enzymes)

BamHI (Boehringer)

XbaI (Boehringer)

In this case  
 same buffer used.

for 500 $\mu$ l tube

Vortex - give a quick spin Add last mix thoroughly & quick spin	{	DNA	- 2.5 $\mu$ l
		BSA	0.5 $\mu$ l
		10 $\times$ BamHI Bf	0.5 $\mu$ l
		XbaI	1.0 $\mu$ l
		BamHI	0.5 $\mu$ l

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EXHIBIT 30

Name:

J. Shetty

Date:

9/23/99

Experiment:

Restriction digestion of DNA (plasmid)

077

Digestion of DNA - Sequential digestionCocktail for Xba I

9  $\mu$ l of 10x BF  
 9  $\mu$ l of 1mg/ml BSA  
 19.5  $\mu$ l of H<sub>2</sub>O  
 9  $\mu$ l of Xba I

Add these,  
 cool & then  
 add  
 enzyme.

prepared  
 for 18  
 reactions

Taken

1  $\mu$ l ofDNA + 4  $\mu$ l of  
cocktail.

mixed with pipette tip.

37°C

- 45 hrs

Bam HICocktail for Bam HI

1.8  $\mu$ l 5M NaCl - to bring the sodium conc  
 to 200 mM (?)  
 9  $\mu$ l 10x Bam HI BF  
 9  $\mu$ l Bam HI  
 9  $\mu$ l 1mg/ml BSA  
 61.2  $\mu$ l H<sub>2</sub>O

prepared  
 for 18 reactions

Added 5  $\mu$ l each to  
 tubes

= 37°C

O/N

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Name:

J. Shetty

Experiment:

Agarose gel electrophoresis of digested DNA

Date: 9/24/99

078

# 1.2% Agarose Gels

Lanes:

- ① 1-M
- ② 1-2
- ③ 1-3 - showed around 1 kb DNA band
- ④ 1-4
- ⑤ 3-1-M
- ⑥ 3-2 - showed around 900 b pair product
- ⑦ 4-1
- ⑧ 4-2 - showed around 1 kb product

①-② and ④-②

Given for Sequencing

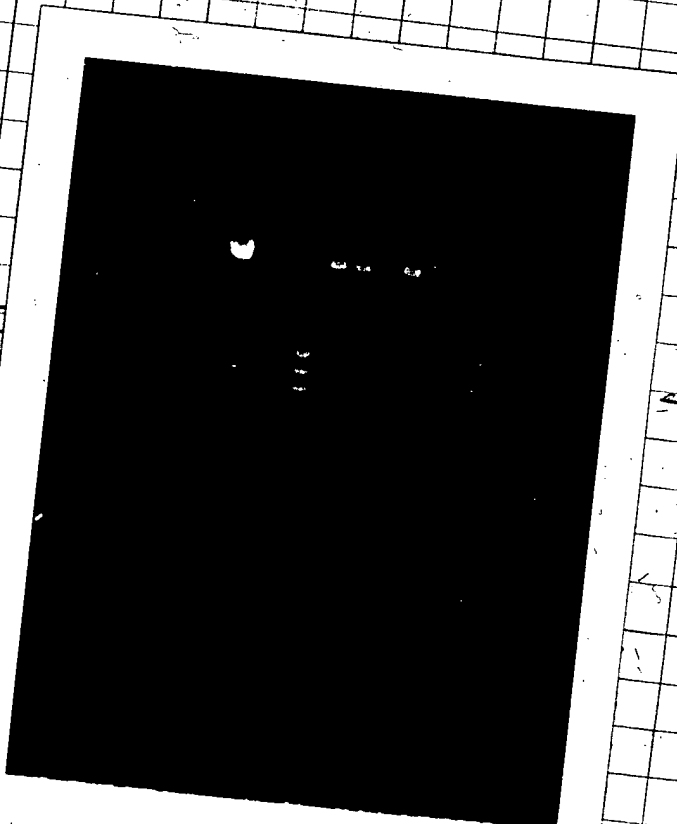
DNA - 31

Forward primer 15A - 23mer

Rev primer 21A - 21mer

16A

1-078  
872  
603



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EXHIBIT 32

Y Research



NCHGR



Got the Sequence. back.

Sequence - bad - ~~as~~ -

- Decided to give more DNA -  
for 1-2

DNA :	11.5 $\lambda$
Ex. pos m :	1.5 $\lambda$
H <sub>2</sub> O	3.0 $\lambda$
	<u>16.1</u>

A culture of bacterial cells - with  
clone - (1-2) and (4-2) (saved  
earlier) - inoculated to LB  
25 ml culture with asup. and  
Soc. Citrate. (10 mM) (75  $\mu$ g/ml)  
O/N

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Name:

J. Shetty

Date: 9/25/99

080

Experiment:

Plasmid isolation

# Protocol - preparation of plasmid DNA.

25 ml culture



Spun into 2 15 ml tubes



Spin - 3000 rpm.

~~the~~ Supernatant discard completely



pellet.



processed for DNA isolation using Qiagen kit



pellet obtained at the final step - ~~carefully~~ ~~washed~~ carefully washed with 2 ml of EtOH - ~~not~~ chilled



pellet dried completely



resuspended in 80  $\mu$ l of d.H<sub>2</sub>O.



saved in -70°C.

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Name: Jagathpala Shetty Date: 10/5/99.  
Experiment: Sequence for CSB / 1-2 F

082

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Sequence for 1-2 F - Obtained -

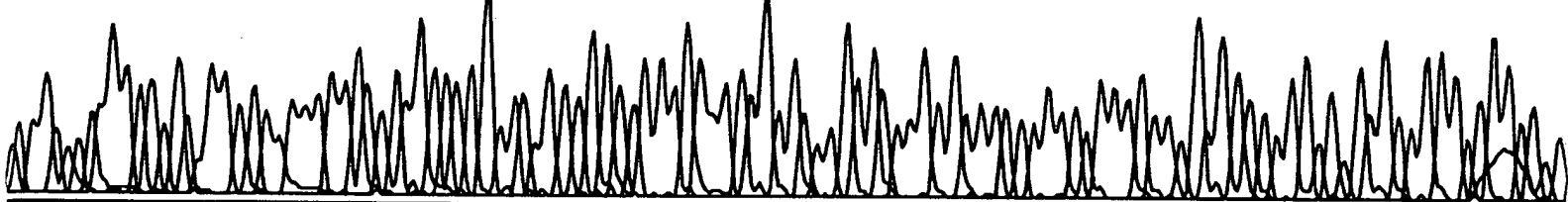
7 17-99-13259  
3.3 1-2 F  
99-13259  
3.2 Lane 17

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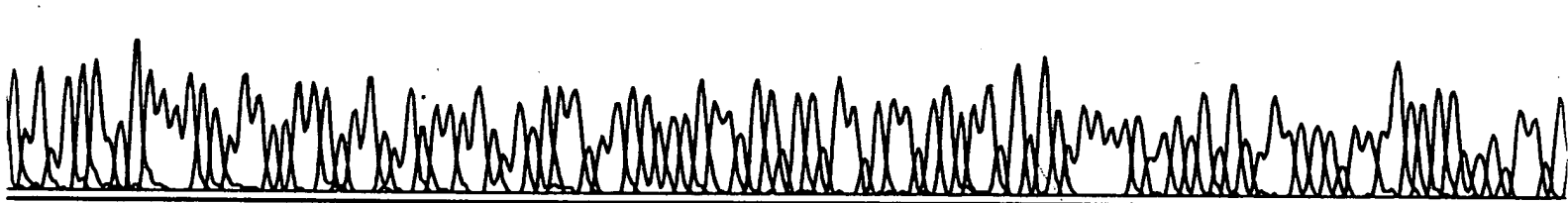
Signal G:402 A:243 T:156 C:338  
DT (BD Set Any-Primer)  
dRmatrix61697  
Points 938 to 10624 Pk 1 Loc: 938

Page  
Tue, Oct 5, 1999  
Mon, Oct 4, 1999  
Spacing: 8.9

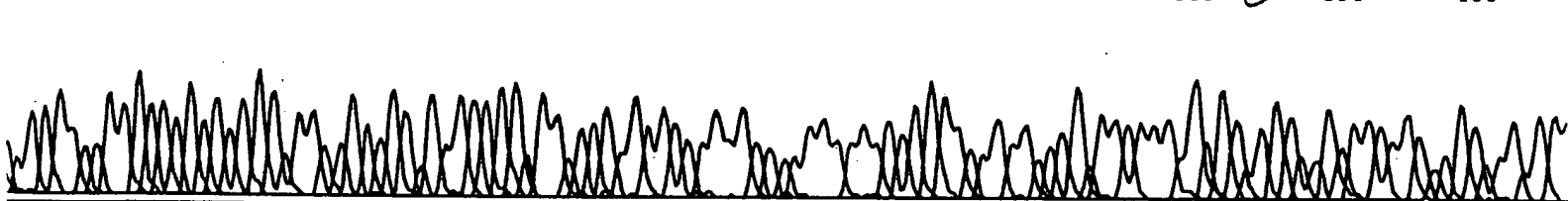
ATC GCGAAGGAGCCAGGCGC GT TGGCA AG GAGGACA CTC CAGG CCTGAC CCTGGGAGGC CAGGAC CAGGCGC CAAGTCCCGTGGCAAG AGG AGTC CTCAG AGGTC CT TCAT TCAGC  
10 20 30 40 50 60 70 80 90 100 110 120



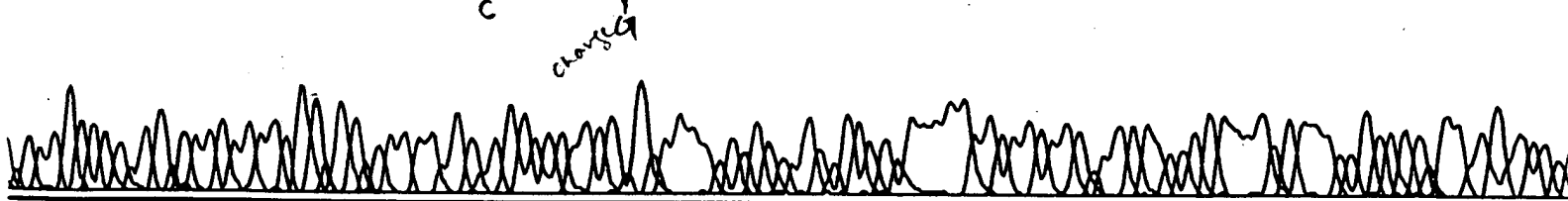
CGCC CTGCT TGGGCA GGGTCA AC GCG CAGGCC CCGCAT GGTCT CT GT GCTG CT TCT TCTGCTGATG CT TCT GCGCCCAAGGCAC CA CCGGC GTCA AGGACT GCGTC TTCT  
160 170 180 190 200 210 220 230 240 250 260



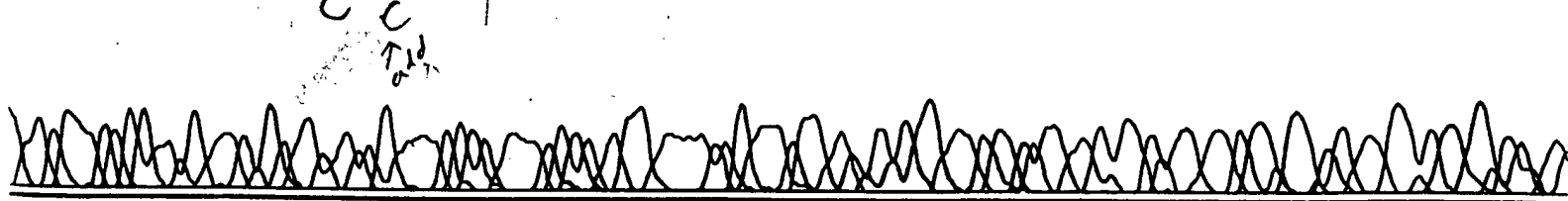
CTCTG GTACCTACAT GCAC TGTGGCGA TGA CGA GGAATCT CT TCACAG GC CA CCGGGTC GCGCCGGTAC TG GTCCGGTCA TCACAAAGGCTG CTTCGA GCCAC CAGCT GCG GCGCT  
300 310 320 330 340 350 360 370 380 390 400



CTACTTAC GCGTACCAC CAACT GCTGAC CCGT CG CTGTGTACAA GCGCCGAGCA GCGAGACAGTGGGGT CAGCAC CA CT GCG ACT GGGCT GGGAT GCT GCTTCTTCAAG  
440 450 460 470 480 490 500 510 520 530 540 550



GGCTGGGCTGT TTTCCAGATCCGCTCTTCCCATGAGCCCA TGTCT T CCGCCTAAATGGGCAAGAG GCGCTGGGCAACCTTTCGCGGCTGCTTATTCTTAAAGTGTCA  
590 600 610 620 630 640 650 660 670 680 690 700



Important: Place card under blue copy.

EXHIBIT 35

Name: Jagdhpala Shetty Date: 10/6/99  
Experiment: Sequence for C58

083

Sequence for 1-2 R & 4-2 R obtained.

However sequence were bad.

They were resubmitted with a

request for  $p(dt) > p(dt)_{20N}$

primer

However the sequence results of

clone 1-2 F yielded enough

(good) sequence to deduce the complete

open reading frame for C58!

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Name:

Jagathpala Shetty

Date:

10/6/99

084

Experiment:

Nucleotide and deduced  
amino acid sequence for C58

Complete ORF of C58 contained 372 base pairs encoding 124 amino acids with a predicted Mol. Wt. of 13 and a predicted pI of 5.5. Sequences of one of the tryptic peptides originating from the cored 2-D spot was found embedded in the ORF (Blue boxes).

GTCCCGGATCCGCGAGGGACGCAGGGCGTTGGGAACAGAGGACACTCCAGGCGCTGACCC

V P D P R G T Q G V G N R G H S R R \* P -

TGGGAGGCCAGGACCAGGGCCAAAGTCCCGTGGGCAAGAGGAGTCCTCAGAGGTCTTCA

W E A R T R A K V P W A R G V L R G P S -

TTCAGCGGTTCCGGGAGGTCTGGGAAGCCACGGCCTGGCTGGGGCAGGGTCAACGCCGC

F S G S G R S G K P T A W L G Q G Q R R -

CAGGCCGCCATGGTCCTGTGCTGGCTGCTGCTTCTGGTGATGGCTCTGCCCCAGGCACG

Q A A M <sup>1</sup> V L C W L L L L V M A L P P G T -

ACGGGCGTCAAGGACTGCGTCTTCTGTGAGCTACCGACTCCATGCAGTGTCTGGTACC

T G V K D C V F C E L T D S M Q C P G T -

TACATGCACTGTGGCGATGACGAGGACTGCTTCACAGGCCACGGGGTCGCCCCGGGCACT

Y M H C G D D E D C F T G H G V A P G T -

GGTCCGGTCATCAACAAAGGCTGCCTGCGAGCCACCAGCTGCGGCCTTGAGGAACCCGTC

G P V I N K G C L R A T S C G L E E P V -

AGCTACAGGGGCGTCACCTACAGCCTCACCACCAACTGCTGCACCGGCCGCTGTGTAAC

S Y R G V T Y S L T T N C C T G R L C N -

AGAGCCCCGAGCAGCCAGACAGTGGGGGCCACCACCAGCCTGGCACTGGGGCTGGGTATG

R A P S S Q T V G A T T S L A L G L G M -

CTGCTTCCTCCACGTTTGCTGTGACCAACAGGGAGGACAGGGCCTGGGACTGTTCTTCCA

L L P P R L <sup>124</sup> P T G R T G P G T V L P -

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EXHIBIT 37

National Brand

Laboratory Research

Name:

Jagathpala Shetty

Date:

2/10/99

Experiment:

Recombinant expression of C58

085

Primers ordered for the generation  
of C58 - OX - DNA - with Xho and  
Nco site on either side to be  
ligated to a PET 20 vector

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EXHIBIT 38

Oratory Research

Laboratory Research

National Brand

Name:

Jagah polu Shethi

Date: 11/2/99

Experiment:

PCR to generate C58 complete ORF

086

PCR reaction

use C 58 PET primers.

Bottom~~Top~~

Top

3.025

3.325

4.55

2

4 dNTP

2

Mg

1.25 (pmol/l)

GSP-F' (C58 PET F)

1.25 (20 pmol/l)

GSP-R' (C58 PET R)

0.425

1.20

7.95

C DNA

2

poly dle

0.5

① C58 PET-R-60 pmol/l

② C58 PET-R-20 pmol/l

PCR programme (JSL)

① 94°C 2:00

② 94°C 1:30

③ 72°C 2:30

Δ-14 cycle

11 times

④ Go to ②

370

⑤ 94°C 1:30

⑥ 60°C 1:30

⑦ 72°C 2:00

27x

⑧ Go to ⑤

⑨ 72°C 18:00

⑩ 4°C ∞

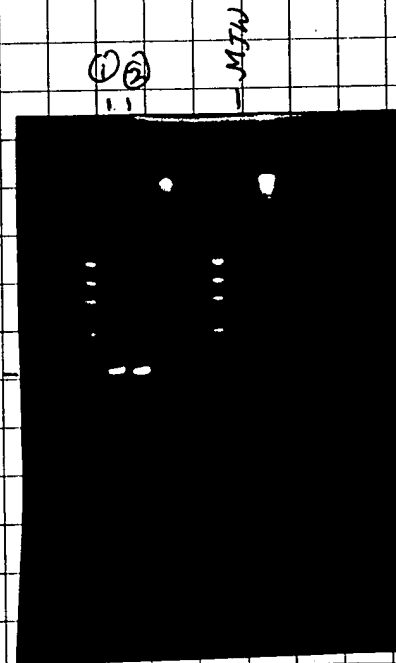
⑪ END

Result: Gave the expected size product

Important: Place card under blue copy.

EXHIBIT 39

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Name:

Jagathpala Sheth

Date:

11/16/99

Experiment:

089

Digestion of CS8-PET-DNA with  $XhoI$  and  $NcoI$  endonucleases.

DNA received in 90 $\lambda$   $\rightarrow$  auto-evaporated to  $\approx 15\lambda$ .

Digested with  $XhoI$  &  $NcoI$  as follows.

	DNA	15 $\lambda$
(Parrage) bf	D (10 $\lambda$ )	20.5 $\lambda$
	<del>H<sub>2</sub>O</del>	30.5 $\lambda$
Bovinger	$XhoI$	2 $\lambda$
NEB.	$NcoI$	2 $\lambda$
		<u>25<math>\lambda</math></u>

$37^\circ C$  O/N  
with salt.

11/17

Amplification of DNA by gel electrophoresis

loaded all 25 $\lambda$  + 4 $\lambda$  of loading bf.  
used 5 wells (covered with tape) 5 weeks.

DNA preserved in  $\approx 80\lambda$  of d-H<sub>2</sub>O

↓  
Desalted using Ambion x 2 times

↓  
recovered in 60 $\lambda$

↓  
Quantified.

Important:

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EXHIBIT 40



Name:

Josephale Shethi

Date:

11/17/99

Experiment:

090

Samples: ① 5 $\lambda$  g DNA + 1 $\lambda$  g loading bf.

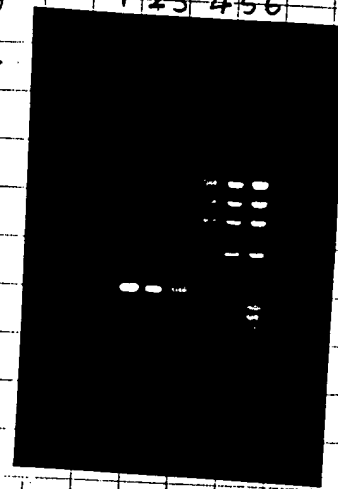
② 3 $\lambda$  g DNA + 2 $\lambda$

③ 1 $\lambda$  g DNA + 4 $\lambda$  -

④ 0.5 $\lambda$  g marker

⑤ 0.1 $\lambda$  g marker

⑥ 1.5 $\lambda$  g marker



Actual amount of DNA:  $\frac{125 \times 1 \times 0.603}{5.386} \times 1$

= 13.99 ng/ $\lambda$

Total vol: 50 $\lambda$ . i.e.: 699.73 ng

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10/809,654

EXHIBIT 41



Laboratory Research

Important: Please read

Name:

Jangatpala Sheth

Date: 11/18/99

Experiment:

091

Ligation

NCO/ Xho cut	{	pET C58 -	3 $\lambda$	
		pET 286+	2 $\lambda$	
		10x lig bf.	2 $\lambda$	(also contain
		H <sub>2</sub> O	12.5 $\lambda$	& ATP)
		ligase	0.5 $\lambda$	
			20 $\lambda$	
				↓ 14°C
				0/N

After joining

DNA, 30 & vector  
warmed to ~ 50°C in  
water bath and for  
30 sec. and out cooled  
at 25.

Then added bf lig-bf  
mix thoroughly and  
finally add ligase on  
ice.

Culture of host strain bacteria (Novo Blue.  
DE3 BL-2)

1 ml of LB + spec of strain - 0/N 37°C.

11/19/99

Preparation of Competent cells  
and Transformation of DNA to  
host strains

- ① Culture diluted 5 times and checked  
O.D. (622nm) = 0.8  
Novabine = 0.8
- ② Diluted the culture back down to

Important:

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10/809.654

EXHIBIT 42

0.1 OD in 1.25 ml LB + 12.5 ml mgcb/soc

ie: 170x ~~25~~ of culture used.

Grown to  $\approx 0.55$  OD at 37°C Shaking

Centrifuged, remove supernatant

Redissolved in 0.4 ml TFB (from NJW)  
and keep in ice - 10'

Centrifuged, dissolve 100x of TFB

Add 3.5 ml DMSO (from NJW)

Keep in ice 10'

Add 3.5 ml DMSO again  
Keep in ice 10'

Add 10x each of ligation mixture  
& kept in ice - 30'

Given a heat shock @ 42°C for 90 sec.

Kept in ice 2'

Added 300x LB + Mgcb/soc + Glucose  
3x 20mM  
(ie: 8x for 1M)

Shaken at 37°C - 1 Hr.

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EXHIBIT 43

Name:

Jyothipala Sneh

Date:

11/19/99

Experiment:

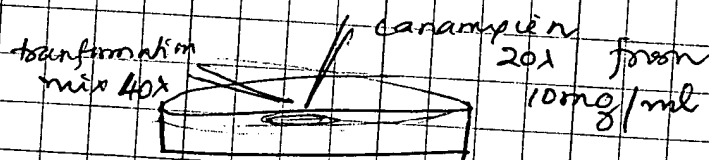
093

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Plating.

Plating was done on LB-agar plates.

from each tube 3 plates were plated for BL-1 & numone each at 40x, 360x & 45x using 10  $\mu$ s/ml of canamycin as the selection



↓  
Spread.

↓  
37°C O/N.

11/20/99

One colony picked from plates 40x 360x  
① & ⑤ from each strain and  
a 3ml O/N culture made in LB + tetracycline + canamycin.

10  $\mu$ s/ml

Name:

Jagathpala Shetty

Date: 11/22/99

Experiment:

Plasmid isolation

094

## Isolation of Plasmid DNA

Isolation made by following the protocol on the Qiagen kit for miniprep.

- ① 3 ml of culture centrifuged in 1.5 ml microfuge tubes at 2 steps.

- ↓  
② Add 0.3 ml of bf P1 to the pellet dislodge the pellet with P200 micropipette.

- ↓  
③ Add 0.3 ml of bf P2 invert 4-6 times at 4°C - Sit - 5 min

- ↓  
④ Take P3 from 4°C and add 0.3 ml to tubes and invert 4-6 times and place it on ice - 5 minutes

- ↓ spin 10 min  
⑤ Meanwhile set up the Qiagen column. Equilibrate the column with 1 ml of QBT

↓  
Take the supernatant from step 4 carefully and load to the column.

- ↓  
⑥ Wash the column with 1 ml X 4 of QC. wait till last drop drops off.

Important:

EXHIBIT 45

10/809,654

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Name: Jagathpala Shetty

Experiment:

Date: 11/21/99

095

- BEST AVAILABLE COPY
- ⑦ Elute DNA in 0.08 ml of at QF  
wash till the last drop  
↓
  - ⑧ Add 0.50 ml of isopropanol  
↓
  - ⑨ Spin for 30 minutes at 10,000 rpm  
↓
  - ⑩ Remove sup. with Gene tipped  
piston pipette
  - ⑪ Carefully wash the pellet with  
200  $\mu$ l of chilled 70% ethanol.  
↓
  - ⑫ Air dry.

~~11/21/99~~

Resuspend the DNA in 20  $\mu$ l  
each of sterile water.  
mix at 4°C for 15-20 min

EXHIBIT 46

Name:

Jangathpala Shethi

Date:

11/22/99

Experiment:

096

Digestion of plasmid DNA with XhoI and  
NotI.

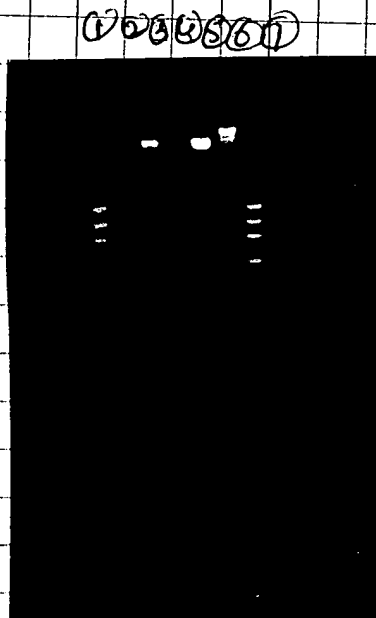
	H <sub>2</sub> O	2.5 $\mu$
	DNA	1 $\mu$
(Boehringer)	XhoI	1 $\mu$
(Nobis)	NotI	1 $\mu$
(Promega)	Bf D (10x)	0.5 $\mu$
		<u>5 <math>\mu</math></u>

} - 37°C O/N

11/23/99

2% agarose gel electrophoresis of  
digested DNA

- ① Marker  $\phi$
- ② B2-21-①
- ③ B2-21-②
- ④ Nov BI ①
- ⑤ Nov BI ②
- ⑥ Marker  $\rightarrow$  Hind  $\phi$
- ⑦ Marker  $\phi$



clone #④ (Nov BI-②)  
A clone of the right size consent.  
A Colony stock of the same - done

10/809,654

Important: Place card under blue copy.

EXHIBIT 4

National Grand

Laboratory Research

DNA from  
clone #4. Nara. Blue - ② = was given  
for sequencing.

① DNA : 8  $\mu$   
T7 terminator : 2  $\mu$  (5 pmoles/ $\mu$ )  
H<sub>2</sub>O : 6  $\mu$   
16  $\mu$

② DNA : 8  $\mu$   
T7 promoter : — requested from Bank  
H<sub>2</sub>O : 4  $\mu$   
12  $\mu$

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Name: Jagadhyala Sheth Date: 11/23/05  
Experiment: Sequence of CS8 in PET 285 after ligation 098

(Linear) MAP of: petc58.promoter.dna check: 7309 from: 1 to: 663  
DNA sequence of pET28b-c58.novablue. with T7 promoter as the primer  
transformed on 11-19-99.

With 2 enzymes: NCOI XHOI

November 29, 1999 14:35 ..

NcoI

1 GGATAACAATTCCCTCTAGAAATAATTTGTTTAACTTTAAGAAGGAGATATACCATGG  
 CCTATTGTTAAGGGGAGATCTTTATTAACAAATTTGAAATCTTCTCTATATGGTACC 60  
 I T I D

I T I P L \* K \* F C L T L R R R Y T M V -  
 TCCTGTGCTGGCTGCTGCTTCTGGTGATGGCTCTGCCCCAGGCACGACGGGCGTCAAGG  
 AGGACACGACCGACGACGAAGACCACTACCGAGACGGGGTCCGTGCTGCCCGCAGTTCC  
 L C W L T

L C W L L L L V M A L P P G T T G V K D -  
 121 ACTGCGTCTTCTGTGAGCTCACCAGCTCCATGCAGTGTCTTGGTACCTACATGCAGCTGTG  
 TGACGCGAAGACACTCGAGTGGCTGAGGTACGTCACAGGACCATGGATGTACGTGACAC 180  
 C V E C E

C V F C E L T D S M Q C P G T Y M H C G -  
 181 GCGATGACGAGGACTGCTTCACAGGCCACGGGGTCGCCCGGGCACTGGTCCGGTCATCA  
 CGCTACTGCTCCTGACGAAGTGTCGGTGCCCCAGCGGGGCCCGTGACCAGGCCAGTAGT 240  
 D D E D C

D D E D C F T G H G V A P G T G P V I N -  
 241 ACAAAGGCTGCCTCGCAGCCACCAGCTGCGGCCTTGAGGAACCCGTCAGCTACAGGGGCG  
 TGTTCGCAGCGACGCTCGGTGGTCGACGCCGGAATCCCTGGGCAGTCGATGTCCTCCCGC 300  
 K G C V D

K G C L R A T S C G L E E P V S Y R G V -  
 301 TCACCTACAGCCTCACCACCAACTGCTGCACCGCGCGCTGTGTAACAGAGCCCCGAGCA  
 AGTGATGTGCGAGTGGTGTGACGACGTGGCGCGGACACATTGTCTCGGGGCTCGT 360  
 T Y S I -

T Y S L T T N C C T G R L C N R A P S S -  
 361 GCCAGACAGTGGGGGCCACCACCGCTGGCACTGGGGCTGGGTATGCTGCTTCTCTCCAC  
 CGGTCTGTACCCCCGGTGGTGGTCGGACCGTGACCCCGACCCATACGACGAAGGAGGTG 420  
 O T V C

Q T V G A T T S L A L G L G M L L P P R -  
XhoI  
421 GTTGTGCTGCTCGAGCACCACCACCACCACCTGAGATCCGGCTGCTAACAAAGCCCGAA

CAAACGACGAGCTCGTGGTGGTGGTGGTGGTGACTCTAGGCCGACGATTGTTCGGGCCT  
L L L E H H H H H H \* D P A A N K A R K -  
AGGAAGCTGAGTTGGCTGCTGCCACCCTGAGCAATAACTAGCATAACCCCTTGGGGCCT

TCCTTCGACTCAACCGACGACGGTGGCGACTCGTTATTGATCGTATTGGGAACCCCGGA  
E A E L A A A T A E Q \* L A \* P L G A S -  
CTAAACGGGTCTTGAGGGGTTTTTGTCTGAAAGGAGGA ACTATATCCGGATTGGCGAATG

GATTGCCCAGAACTCCCCAAAAACGACTTTCCTCCTTGATATAGGCCTAACCGCTTAC  
 K R V L R G F L L K G G T I S G L A N G

C58- is successfully ligated  
to the pET28b Vector

**10/809,654**

EXHIBIT 49

National Brand

Laboratory Research

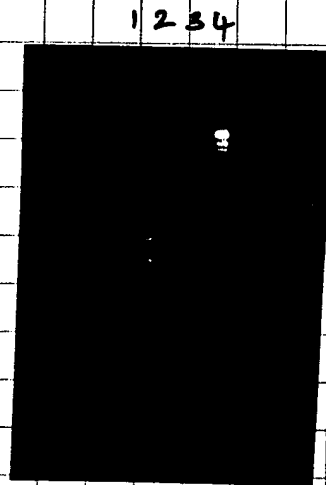
A O/V culture from pET283-C58-NvaBlue(#4)  
was made in tubes  
(3 ml each)  
↓  
plasmid DNA isolated.

11/26/99

11/29/99 A 2% agarose gel run.

- ① Marker
- ② tube # 1 from pET 283-C58-NvaBlue #4
- ③ tube # 2 from " " "
- ④ Marker

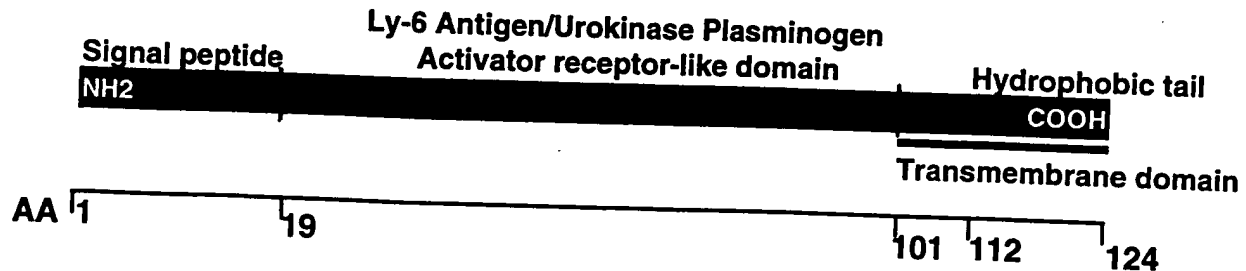
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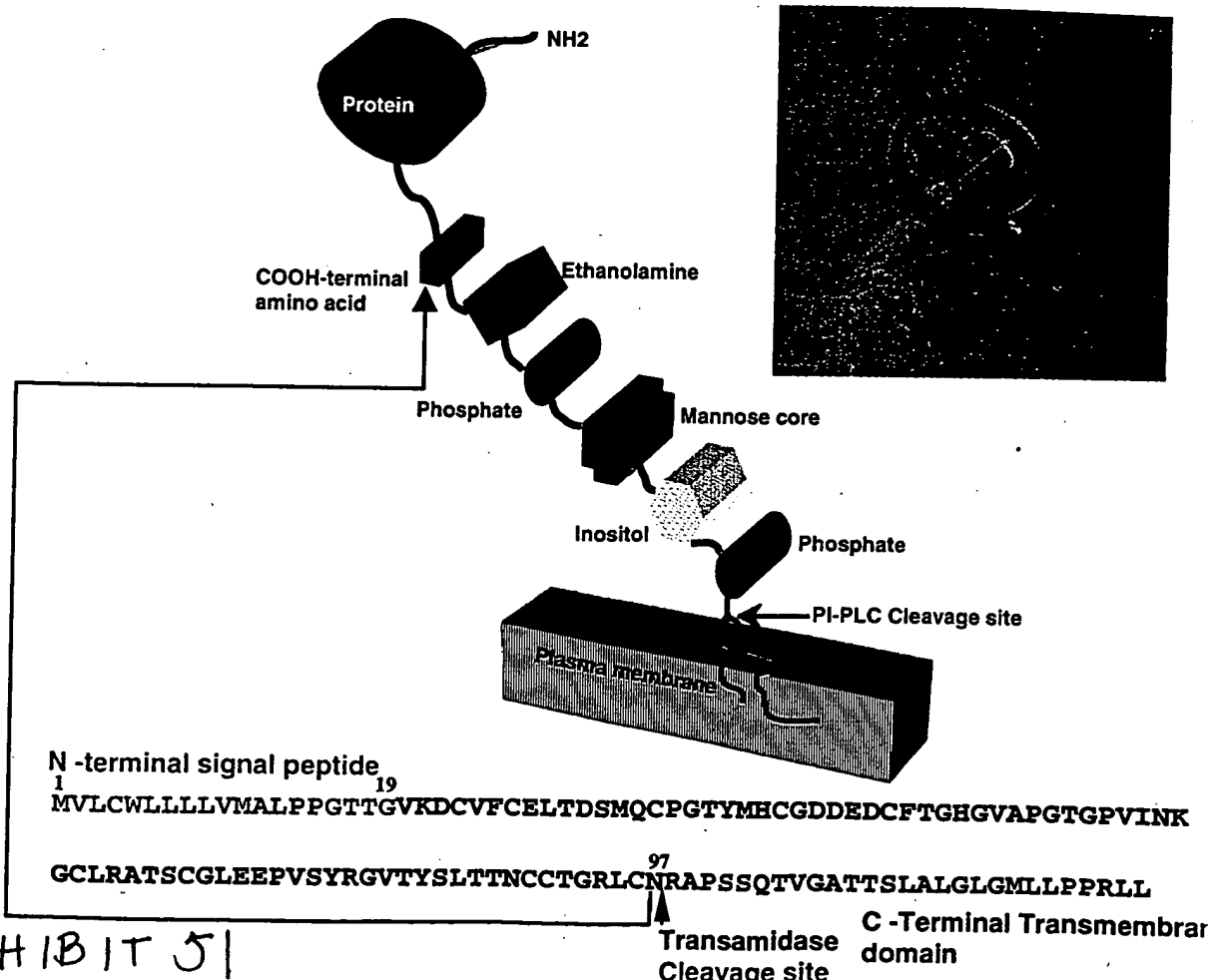
The host strains bearing the plasmid  
gone bad. It was decided to  
streak a plate, force a single colony  
and make a glycerol stock of  
the construct.

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Fig. 8. Proposed Architecture of C58



C58 is GPI anchored - It has a signal peptide  
 a ~~trans~~ C-terminal transmembrane domain and a  
 transamidase cleavage site!



Name:

Tagakpala Sheth

Date:

11/23/99

100

Experiment:

Sequence analysis of C58

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Sequence alignment of C58  
with other Ly6/uPAR family  
members.

C58 (24-98): VFCELTDSMQCPGTYMECGDDEDCFTGHGVAPGTGPVIN---KGCLRATSCGLEEPVSYRGYTYSLTTNCCTGRLCNRA  
 CD59-AOTTR (12-126): CPYPTTQ---CTMTTNTCTSNLDSCLIARA-GSRVYYR-----CWKFEDCTFSRYSNQLSEN-ELKYYCCKKNLCNPN  
 CD59-CALSQ (12-126): CPYSTAR---CTTTTNTCTSNLDSCLIARA-GLRVYYR-----CWKFEDCTFRQLSNQLSEN-ELKYHCCRENLCNPN  
 CD59-SAISC (12-128): CPLPTMESMECTASTNCTSNLDSCLIARA-GSGVYYR-----CWKFDDCSFKRISNQLSET-QLKYHCCCKKNLCNPN  
 CD59-CERAE (12-126): CPNPPTD---CKTAINCSSGFDTCIARA-GLQVYNQ-----CWKFANCFNNDISTLLKES-ELQYFCKCKDLNPN  
 CD59-PAPSP (12-124): CPNPPTN---CKTAINCSSGFDTCIARA-GLQVYNQ-----CWKFANCFNNDISTLLKES-ELQYFCKCKDLNPN  
 CD59-HUMAN (12-126): CPNPPTAD---CKTAVNCSSGFDTCIARA-GLQVYNQ-----CWKFANCFNNDISTLLKES-ELQYFCKCKDLNPN  
 CD59-HSVSA (7-117): CSHSTMQ---CTTSTCTSNLDSCLIARA-GSGVYYR-----CWKFANCFNNDISTLLKES-ELQYFCKCKDLNPN  
 CD59-PIG (12-123): CINPAGS---CTTAMNCSSGFDTCIARA-GLQVYNQ-----CWKFANCFNNDISTLLKES-ELQYFCKCKDLNPN  
 CD59-RAT: (9-120): CLDFV-SS---CKTNTCTSPNLDACLVAVS-GKQVYQQ-----CWRPDCNAKFIILSRLEIA-NVQYRCCQADLCNPN  
 LYGA-MOUSE (2-134): CYGVVFT-SCP-SITCPYPDGVCVTQEAIVIVDSQTRKVKNNLCPLPFPNIEZMEILGTV-NVNTSCCKEDLCNA-  
 LYGF-MOUSE (11-107): CLGVSLGI-ACK-SITCPYPDAVCISQQVELIVDSQRRKVKNNLCPLPFPNIEZMEILGTV-NVNTSCCKEDLCNA-  
 LYGC-MOUSE (2-131): CYGVPIET-SCP-AVTCRASDGFCIAQNIELIEDSQRRLKATROCLSPCPAGVP---IKDPNI-RERTSCCSEDLCNA-  
 LYGE-MOUSE (11-107): CTDQKNNI-NCLWPYSCQEKDHYCITLSAAAGFGN-YNLGYTLNKGCSPICPSENYNLGYA-SYNSYCCQSSFCNPN  
 E48A-HUMAN (21-93): CTSSSN---CKHSYCPASSRFCKTTNTYEPILGNLYK---KDCAESCTPSYTLQGGYSSG-TSSTQCCQEDLCNPN  
 THYB-MOUSE (3-117): CTNSAN---CKNPQYCPSNFYFCKTTNTYEPILGNLYK---KDCAESCTPSYTLQGGYSSG-TSSTQCCQEDLCNPN  
 UPAR-RAT (17-132): CESNQD---CLYECCALGQ---DLCRTTYLREWEDAELEYYTRGLCHKEKTNRTMSYRMGSYIYSLTETTCATNLCNPN  
 UPAR-MOUSE (14-131): CESNQD---CLYECCALGQ---DLCRTTYLREWEDAELEYYTRGLCHKEKTNRTMSYRMGSYIYSLTETTCATNLCNPN  
 UPAR-HUMAN (14-129): CKTNGD---CRYECCALGQ---DLCRTTYLREWEDAELEYYTRGLCHKEKTNRTMSYRMGSYIYSLTETTCATNLCNPN  
 UPAR-BOVIN (5-127): CENTTS---CSYEECTFGQ---DLCRTTYLSYWECCGNNMYRKGCTHPDKTNRSMSYRAADQIITLSETYCRSDLCNPN

Name: Jagadipala Sheth

Date: 11-29-99.

Experiment: Bacterial expression of C58

01

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Bacterial cells (NOVA BLUE) containing  
the construct pET 28b - C58 (#4)  
was streaked on a agar plate (LB)

11/30/

produced a single colony and inoculated  
to 1ml LB broth

↓  
A glycerol stock made  
(1ml of culture + 150 $\mu$ l of 100% glycerol)

Protein Expression

10 $\mu$ l of the culture from  
above taken - inoculated  
to 2ml LB culture medium  
+  
kanamycin - 10 $\mu$ g/ml

↓  
growing to  $\approx$  0.5 OD  
~~leak~~ at ↓  
4°C O/N  
↓

12/1/99

cultures from above inoculated  
to 20ml culture (LB + Kanamycin)

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Expression - continued  
Exp.

20 ml culture

checked  
O.D.  
600nm  
(200x + 800x 1/2)

0.07 O.D.

induced  
with 1mM IPTG

Stock 200mg/ml (840mM)

4 samples with 0.05 O.D/ml  
saved, at 0 time  
of induction)

O.D. after 2 hrs = 2.0  
sample collected  
after 2 hrs after  
induction.  
(0.5 O.D/ml  
= 4 samples)

O.D. after 3 hrs = 2.8  
4 0.5 O.D/ml samples  
saved

Kept on ice.

Centrifuge

save pellet  
at freezer

control

20 ml culture

0.07 O.D.

not induced

0.5 O.D/ml  
samples (4)  
saved

sample collected  
after 2 hrs  
after  
0.5 O.D/ml  
= 4 samples

O.D. after 3 hrs = 2.8  
4 0.5 O.D  
samples saved

Kept on ice

Centrifuge

save pellet at  
freezer

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# Bacterial lysate preparation and electrophoresis

- ① total cell preparation
- ② soluble fraction
- ③ insoluble fraction

Total cell: 0.5 OD pellet + 20% of ~~lysate~~ 10 mM Tris, pH 8.0 + 20% of sample buffer  
 Boil to 70°C - 2 min.  
 Centrifuge  
 Load everything.

② Preparation of soluble & insoluble fractions.  
 Used Rongbuster - novagen

0.5 OD/ml - pellet  
 95% of Rongbuster  
 Vortex  
 Shaker 10 min  
 Centrifuge

pellet ← Supernatant → soluble fraction  
 add Rongbuster 20%  
 mild vortex  
 Add 200 µg/ml lysozyme.  
 incubate 5 min.  
 Sample 5t  
 Load

Name:

Jagathnala Shetty

Date:

12/3/99

Experiment:

04

insoluble fraction - continued.

Add 6 vols of 1:10 bugbuster

vortex.

centrifuge

pellet + 1:10 bugbuster

centrifuge

pellet resuspended in  
10 mM Tris + sample buffer.

2 Gels

over

3h. unind.

3h. induced

①

M

T

of one

S21

Inc1

T

S21

Inc1

T

S21

Inc1

M

15% separating gel 4% stacking gel  
run o/p at 150 mV

Gel coomassie stained.



Name: Jagadpala Shetty

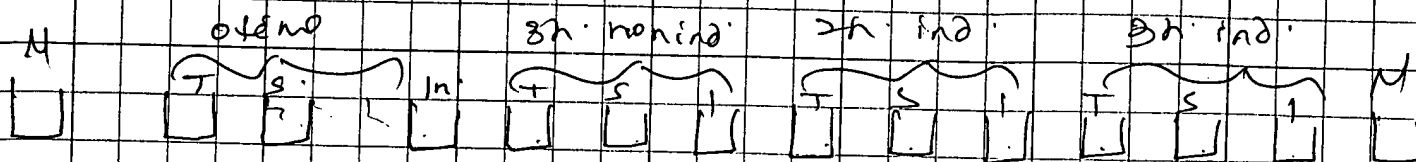
Date: 12/4/99

Experiment:

05

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Gal # 2.



Gal. transferred to a nitrocellulose membrane

12/6/99

Western Blotting of the membrane

used 1:1000 dilution of Ni-NTA conjugate.

↓  
developed by ECL  
& TMB.

Blot was prestained with  
pH 5.5.  
before probing.

Name: Jagathpala Sheth

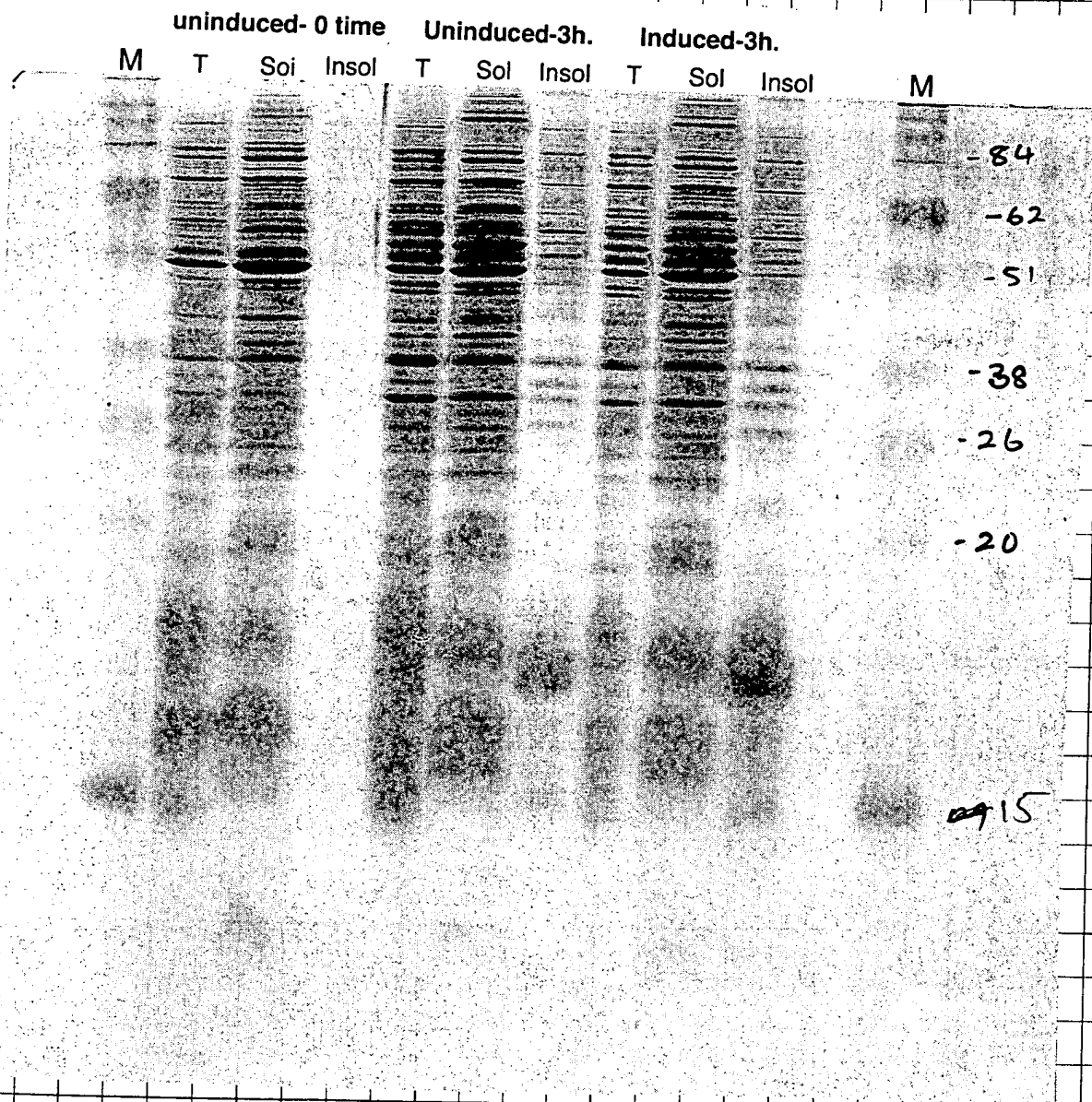
Date: 12/4/99

Experiment:

06

Gel # 1 : Coomassie stained gel

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NO expression!

Important: Place card under blue copy. EXHIBIT 58

Name: Jagathpala Shetty

Date: 12/10/99

Experiment: C 58 - Rec. expression

09

- (1) Nova blue - PET 28b - control - } used 7.6 mg/l  
(2) BL-21 - PET 28b - control - } 1.5 ml 28b from 570 ml 7.6 mg/l  
(3) BL 21 - C-58-28b - transformed with C-58 plasmid DNA - 1X
- Plated 360  $\mu$  & 40  $\mu$

37°C o/n

12/11/99 Plates examined and kept at 4°C

12/12/99 A single colony from one of the plates from each group - inoculated - 1 ml o/n culture made

12/12/99 (1) Glycerol stock of all the 3 made.

(2) A 2 ml culture for PET 28b-C58 & PET 28b - control made. till the OD reaches 1.005  
↓  
Kept at 4°C o/n

Name: Jagathpala Shetty Date: 12/13/99  
Experiment: CS8- Rec. expression

10

documented 2 ml of inoculum from  
control (empty vector) and CS8+ vector. Nowable  
to 20 ml culture.

↓  
At O.D = 0.7 added 1 mM IPTG  
to the culture.  
Sample saved ~~at~~ before induction  
(0.5 O.D/ml samples)

↓  
After 2 hrs. - samples saved  
(0.5 O.D samples)

↓  
After 3 hrs. flasks taken out  
chilled - ice.

↓  
0.5 O.D samples - aliquoted - centrifuged  
Rest of the samples - centrifuged  
and saved.

↓  
pellets saved at  
-20°C

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# SDS- PAGE of the culture Bacterial lysate

Gel: 15%

## Sample preparation:

used bug buster - pellets dissolved  
 in 30  $\mu$ l of bug buster - vortexed - 5 min.  
 centrifuged  $\rightarrow$  sup.  $\rightarrow$  30  $\mu$ l of sample at  $\frac{90^{\circ}\text{C}}{2\text{min}}$  - load

↓  
 pellet + 30  $\mu$ l bug buster

↓  
 vortex

↓  
 lysozyme 200  $\mu$ g/ml

↓  
 incubate 5 min.

↓  
 Add 180  $\mu$ l of 1:10 bug buster

↓  
 vortex

↓  
 Centrifuge  $4^{\circ}\text{C}$  20 min

↓  
 pellet  $\rightarrow$  add 200  $\mu$ l of

1:10 bug buster

↓  
 pellet  $\rightarrow$  add 200  $\mu$ l of

1:10 bug buster

↓  
 pellet + add 200  $\mu$ l of

1:10 bug buster

Load  
 ↑  
 heat to  $90^{\circ}\text{C}$   
 2 min  
 ↑  
 Add eq. volume  
 of sample  
 buffer to

in this buffer 50  $\mu$ l

Name: Jagathpala Sheth

Date: 12/15/99

Experiment:

12

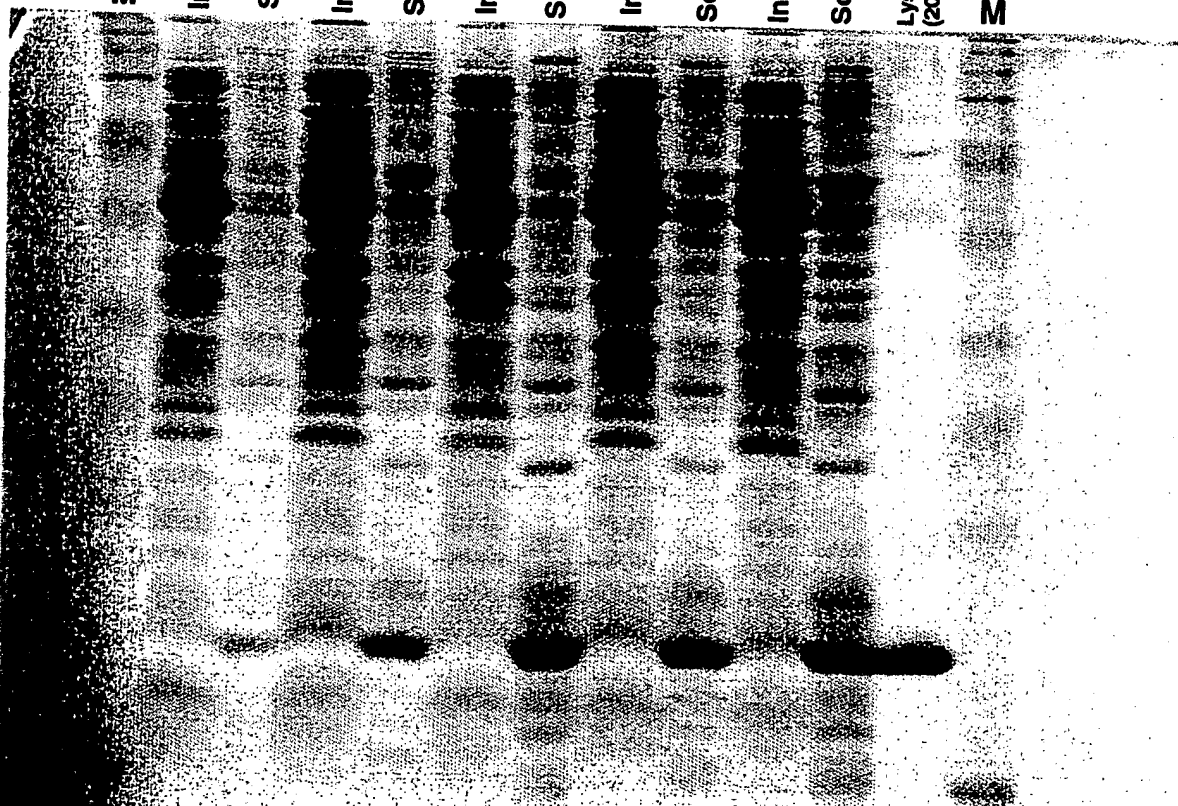
Controls: 200 ng of lysozyme in  
50 mM Tris and sample buffer  
& sets of gels run.

Coomassie  
Staining

Transferred to nitrocellulose  
& probed with anti-NTA  
(1:2000).

TMB

control  
Unind Ind Unind Ind 2h Ind 3h  
Insol Sol Insol Sol Insol Sol Insol Sol Insol Sol  
Lyszyme (200Ug)  
M



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EXHIBIT 62

Name: Jagadhpala Sheth Date: 12/15/99  
 Experiment: SAT- PAGE analysis

13

→ Marker (Gibco)  
 -- S } control (empty vector)  
 -- IN } unind.  
 -- S } control. induced  
 -- IN }  
 -- S } c-58  
 -- IN } uninduced  
 S } c-58  
 IN } induced 2 hrs  
 -- 1 hr 81 }  
 -- 507. } c58  
 -- insoluble. induced 3 hrs.  
 -- ~~insoluble~~ hypoxym 200 mg  
 -- Marker

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Name: Jagathpala Shethi Date: 12/15/99

Experiment: Northern Blot analysis of C58

14

## Northern Blot analysis

Probe: c-58-ORF. The PCR product ~~is~~ of c-58 ORF with Xho-I and Nco-I <sup>5' & 3'</sup> sites at their side was cleaved with above enzyme and purified on agarose to clean off the end fragments.

## Labeling of DNA (Vogelstein's method)

4x of DNA (13.9 ng/μl)  
29.5x H<sub>2</sub>O → Boil - 5 min. in water bath  
10x of OLBT (from MJW)

↓  
Keep at -20°C for a while.

↓  
Add 5x of [ $\alpha^{32}$ P] dCTP

Add 1.5x of Klenow polymerase

↓  
Incubate for a while

↓  
Keep at 37°C O/N

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Name: Jagathpala Sreth Date: 12/15/99  
Experiment: Northern Blot analysis - protocol

15

MTN® Blot User Manual

## I. Introduction continued

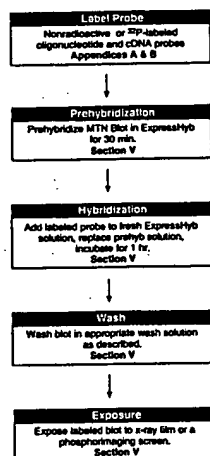


Figure 1. Overview of MTN Blot protocol. Use the  $\beta$ -actin probe to verify that hybridization procedures are working properly and to quantify results.

## II. List of Components

Store unused MTN Blots at room temperature in a sealed plastic bag away from light.  
Store used MTN Blots at 4°C in a sealed plastic bag until needed.  
Store control probe at -20°C.

- 1 MTN Blot
- 100 ng Human  $\beta$ -actin cDNA control probe (2.0 kb) in 20  $\mu$ l of TE buffer (pH 7.5). Sufficient for 2-4 labeling experiments.
- 25 ml ExpressHyb™ Hybridization Solution

## III. Additional Materials Required

- 20X SSC
- 3 M NaCl
- 0.3 M Sodium citrate (pH 7.0)
- Wash Solution 1
- 2X SSC
- 0.05% SDS
- Wash Solution 2
- 0.1X SSC
- 0.1% SDS
- Wash Solution 3
- 2X SSC
- 0.1% SDS

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Protocol # PT1200-1  
Version # P936029

Protocol # PT1200-1  
Version # P936029

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MTN® Blot User Manual

## V. Hybridization of Oligonucleotide & cDNA Probes

For hybridizing radioactively-labeled probes follow Section A. For hybridizing nonradioactively-labeled probes follow Section B.

### A. Hybridization of radioactively-labeled probes

We recommend the following probe concentrations:

- cDNA probes: 2-10 ng/ml or  $1-2 \times 10^5$  cpm/ml.
- Oligonucleotide probes: 20-50 ng/ml or  $1-2 \times 10^7$  cpm/ml.

Note: Higher probe concentrations will reduce hybridization time, but may increase background.

1. Warm ExpressHyb Solution at 68°C, and stir well to completely dissolve any precipitate. For oligonucleotide probes, equilibrate ExpressHyb at 37°C.

2. Prehybridize membranes in a minimum of 5 ml of ExpressHyb Solution, with continuous shaking for 30 min at the appropriate temperature:

For cDNA probes: 68°C

For oligonucleotide probes: 37°C

Note: If you are using hybridization bottles, make sure that the marked side of the membrane is flush against the side of the bottle. Bubbles between the membrane and the bottle can give the appearance of bubbles on the blot.

3. Denature radioactively labeled probes at 95-100°C for 2-5 min. Then chill quickly on ice.

4. Add radiolabeled probe to 5 ml of fresh ExpressHyb, and mix thoroughly.

5. Replace the ExpressHyb Solution with the fresh solution containing the radiolabeled probe. Remove all air bubbles from the container, and make sure ExpressHyb Solution is evenly distributed over the blot.

6. Incubate with continuous shaking for 1 hr at the appropriate temperature:

For cDNA probes: 68°C

For oligonucleotide probes: 37°C

7. Rinse the blot in Wash Solution 1 several times at room temperature. Wash for 30-40 min with continuous agitation; replace the wash solution several times.

8. Wash the blot two times in Wash Solution 2 with continuous shaking for 40 min at the appropriate temperature:

For cDNA probes: 50°C

For oligonucleotide probes: room temperature

9. Remove the blot with forceps and shake off excess wash solution.

Note: Do not allow the membrane to even partially dry. Allowing the membrane to dry can cause high background and will make subsequent probe removal difficult.

## V. Hybridization Protocols continued

10. Immediately cover the blot with plastic wrap. Mount on Whatman 3 MM Chromatography paper. Wrap again with plastic wrap.

11. Expose the MTN Blot using a phosphorimaging screen. The Storm® PhosphorImager (Molecular Dynamics) is suitable for this application. Alternatively, expose to x-ray film at -70°C with two intensifying screens.

12. Strip probe from the blot by incubating the blot in sterile H<sub>2</sub>O containing 0.5% SDS as outlined below.

a. Heat the sterile H<sub>2</sub>O/0.5% SDS solution to 90-100°C.

b. Remove plastic wrap from blot and immediately place in the heated solution. Make sure that exposure to air is minimal.

c. Incubate for 10 min, shaking frequently.

d. Allow the H<sub>2</sub>O to cool for 10 min before removing the blot.

e. Remove the blot and air-dry until it is dry enough to be slipped into a plastic bag. The membrane can be stored at -20°C until needed.

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EXHIBIT 65

Name: Jagathpala Shethi

Date: 10/16/59

Experiment: Northern Blot analysis

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Probe was purified in 0.5 ml of eluting buffer, denatured at  $95^{\circ}\text{C}$  & chill mic.

~~Added to 7 ml of the~~  
Allan same the membrane (from

① A. Plandol, - NPTN - Blot from Clontech - used once, stripped, dried) was incubated with 7 ml of probe hyp soln at  $68^{\circ}\text{C}$  in a plastic bag (sealed) for  $1\frac{1}{2}$  hrs. (carefully Shethi 15)

② Purified probe added to 7 ml of exp. hyp. ~~and~~. The plastic bag was emptied and the ~~solution~~ bag filled with the solution. Sealed carefully and incubated at  $68^{\circ}\text{C}$  for  $1\frac{1}{2}$  hrs.

③ Discard the exp. hyp. soln and wash place it on a dish and wash several times with wash bf 1. (2x SSC, 0.05% SDS) and incubate with the same for 40 min. Replace the wash soln. 3 times (temp. RT)

④ Replace with wash soln. 2. (0.1x SSC, 0.1% SDS,  $50^{\circ}\text{C}$ ) 40 min - 3 changes.

⑤ Take the Blot in little amount of

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Name: Jagathpala Shetty

Date: 12/16/99

Experiment:

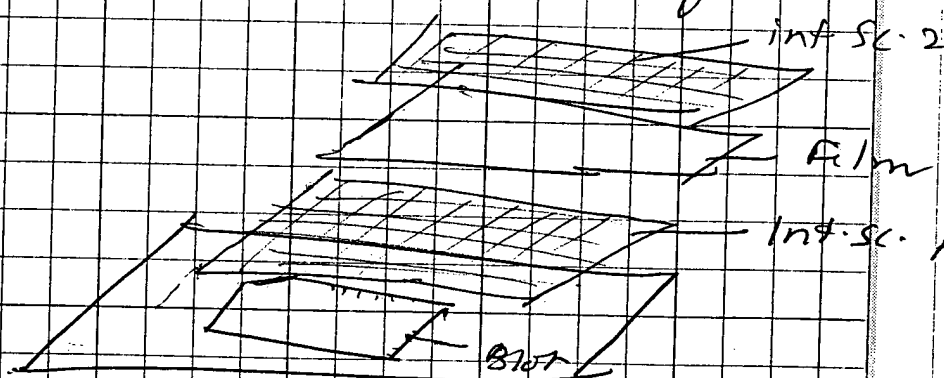
Northern Blot analysis of CS8

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wash buffer. place it on a platform made out of a Whatman paper and a saran wrap.

place another saran wrap on the top of the ~~set~~ blot immediately (do not allow it to be wet). Place the marker spots on the edges.

Place the blot inside the cassette with intensifying screen. expose for 18 hrs.



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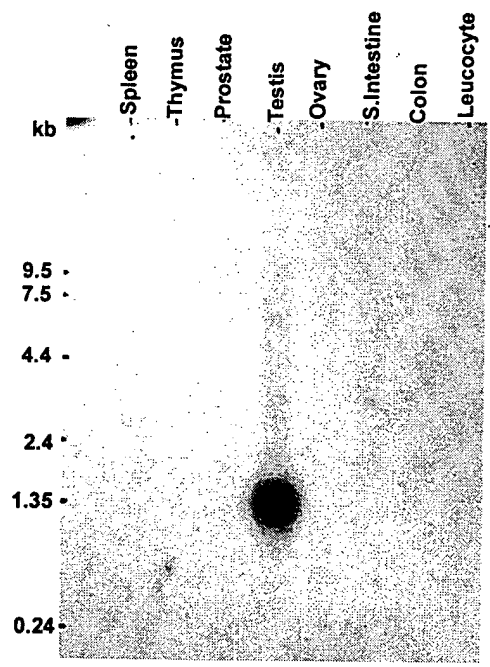
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EXHIBIT 67

Name: Jagathpala Sheth Date: 12/18/99  
Experiment: Northern blot analysis - c58

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MULTIPLE TISSUE NORTHERN  
CONTACT  
developed on 12-17-99.



c58 is expressed only in  
testis!

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Laboratory Research

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EXHIBIT 68

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